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No. 06-

In The
Supreme Court of the United States

CHARLES R. RIEGEL and DONNA S. RIEGEL,
Petitioners,

v.

MEDTRONIC, INC.,
Respondent.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration.

TABLE OF CONTENTS

QUESTION PRESENTED i

TABLE OF AUTHORITIES iv

INTRODUCTION 1

OPINIONS BELOW 3

JURISDICTION 3

STATUTES AND REGULATIONS INVOLVED 4

STATEMENT OF THE CASE 5

A. The Medical Device Amendments 6

B. The Decision in *Medtronic v. Lohr* 9

C. Factual Background and Proceedings Below .. 11

REASONS FOR GRANTING THE WRIT 14

A. The Federal And State Appellate Courts Are Deeply Divided Regarding The Application Of *Medtronic v. Lohr* To The Question Presented. ... 14

B. The Second Circuit's Holding Cannot Be Reconciled With *Lohr*. 19

C. The Decision Below Leaves Patients Injured By The Most Risky Devices With No Remedy—A

Result Inconsistent With The History Of The MDA. 22

CONCLUSION 24

APPENDIX

Court of appeals' decision 1a

District court's decision dated March 14, 2002 ..... 55a

District court's decision dated December 2, 2003 ..... 75a

TABLE OF AUTHORITIES

CASES Pages

Agostini v. Felton,
521 U.S. 203 (1997) 21

Alexander v. Sandoval,
532 U.S. 275 (2001) 21

American Airlines, Inc. v. Wolens,
513 U.S. 219 (1995) 21

Armstrong v. Optical Radiation Corp.,
57 Cal. Rptr. 2d 763 (Cal. App. 1996),
review denied, 1997 Cal. LEXIS 833
(Feb. 19, 1997) 18

Baird v. American Medical Optics,
693 A.2d 904 (N.J. Super., App. Div.),
modified and remanded,
713 A.2d 1019 (N.J. 1997) 17

Bates v. DowAgroSciences,
125 S. Ct. 1788 (2005) 13, 18, 23

Brooks v. Howmedica,
535 U.S. 1056 (2002) 2, 14

Cipollone v. Liggett Group,
505 U.S. 504 (1992) 13, 18

Connelly v. Iolab Corp.,
927 S.W.2d 848 (Mo. 1996),
cert. dismissed, 520 U.S. 1260 (1997) 16

English v. General Electric Co.,
496 U.S. 72 (1990) 22

Fry v. Allergan Medical Optics,
695 A.2d 511 (R.I.),
cert. denied, 522 U.S. 952 (1997) 16, 17

Geier v. American Honda Motor Co.,
529 U.S. 861 (2000) 18

Goodlin v. Medtronic, Inc.,
167 F.3d 1367 (11th Cir. 1999) 2, 3, 15, 19, 23

Goodyear Atomic Corp. v. Miller,
486 U.S. 174 (1988) 13

Green v. Dolsky,
685 A.2d 110 (Pa. 1996),
cert. denied, 520 U.S. 1168 (1997) 16

Haidak v. Collagen Corp.,
67 F. Supp. 2d 21 (D. Mass. 1999) 15

Horn v. Thoratec,
376 F.3d 163 (3d Cir. 2004) 2, 14, 16, 17, 21

Hutto v. Davis,
454 U.S. 370 (1982) 21

Kemp v. Medtronic, Inc.,
231 F.3d 216 (6th Cir. 2000),
cert. denied, 534 U.S. 818 (2001) 2, 14

Kernats v. Smith Industrial Medical System,
669 N.E.2d 1300 (Ill. App.),
appeal denied, 675 N.E.2d 634 (Ill. 1996),
cert. denied, 522 U.S. 1044 (1998) 1, 17

Knisley v. Medtronic,
126 S. Ct. 420 (2005) 2

Lakie v. SmithKline Beecham,
965 F. Supp. 49 (D.D.C. 1997) 15

Martin v. Medtronic, Inc.,
254 F.3d 573 (5th Cir. 2001),
cert. denied, 534 U.S. 1078 (2002) 2, 16

Martin v. Telectronics Pacing Systems, Inc.,
105 F.3d 1090 (6th Cir. 1997),
cert. denied, 522 U.S. 1075 (1998) 16

Maryland v. Wilson,
519 U.S. 408 (1997) 21

Mears v. Marshall,
944 P.2d 984 (Ore. App. 1997),
review denied, 961 P.2d 217 (Ore. 1998) 17

Medtronic, Inc. v. Lohr,
518 U.S. 470 (1996) ..... *passim*

Mitchell v. Collagen Corp.,
126 F.3d 902 (7th Cir. 1997),
cert. denied, 523 U.S. 1020 (1998) 14, 17, 21

Niehoff v. Surgidev,
950 S.W.2d 816 (Ky. 1997),
cert. denied, 523 U.S. 1005 (1998) 2, 3, 14, 16

Oja v. Howmedica,
111 F.3d 782 (10th Cir. 1997) 3, 17, 22

Papike v. Tambrands, Inc.,
107 F.3d 737 (9th Cir. 1997) 17

Quillen v. American Hospital Supply Corp.,
1997 U.S. Dist. LEXIS 6974
(N.D. Okla. Mar. 31, 1997) 15

Silkwood v. Kerr-McGee Corp.,
464 U.S. 238 (1984) 22

Sowell v. Bausch & Lomb,
656 N.Y.S.2d 16 (N.Y. App. Div. 1997) 15

Sprietsma v. Mercury Marine,
537 U.S. 51 (2002) 18, 22

State ex rel Miller v. New Womyn, Inc.,
679 N.W.2d 593 (Iowa 2004) 14, 17

Steele v. Collagen Corp.,
63 Cal. Rptr. 2d 879 (Cal. App. 1997) 16, 17

Walker v. Johnson & Johnson Vision Products, Inc.,
552 N.W.2d 679 (Mich. App. 1996) 16, 17

Weiland v. Telectronics Pacing System, Inc.,
721 N.E.2d 1149 (Ill. 1999) 3, 14, 15

Worthy v. Collagen Corp.,
967 S.W.2d 360 (Tex.),
cert. denied, 524 U.S. 954 (1998) 16

Wutzke v. Schwagler,
940 P.2d 1386 (Wash. App. 1997),
review denied, 953 P.2d 96 (Wash. 1998) 17

STATUTORY MATERIALS

21 U.S.C. § 360c(a) 6

21 U.S.C. § 360c(a)(1)(A) 6

21 U.S.C. § 360c(a)(1)(B) 6

21 U.S.C. § 360c(a)(1)(C) 6

21 U.S.C. § 360c(f)(1)(A) 7

21 U.S.C. § 360e(b)(1)(A) 7

21 U.S.C. § 360e(b)(1)(B) 7

21 U.S.C. § 360j(g) 16

21 U.S.C. § 360k 4

21 U.S.C. § 360k(a) ..... *passim*

21 U.S.C. § 360k(b) 8

28 U.S.C. § 1254(1) 3

28 U.S.C. § 1257 1

P.L. No. 94-295, 90 Stat. 539 (1976) 6

H.R. Rep. 853, 94th Cong., 2d Sess. (1976) 6, 8

121 Cong. Rec. S1640 (Apr. 17, 1976) 6

REGULATIONS

21 C.F.R. § 801.420 ..... 8, 20

21 C.F.R. § 801.430 15

21 C.F.R. § 801.430(c) 6

21 C.F.R. § 801.430(d) 6

21 C.F.R. § 801.430(e) 6

21 C.F.R. § 801.430(f) 8

21 C.F.R. § 808.1 ..... 8, 20

21 C.F.R. § 808.1(d) 4, 8, 11, 15, 20

21 C.F.R. § 808.1(d)(1) 8, 20

21 C.F.R. § 814.20 7

21 C.F.R. § 814.39(a) 7

21 C.F.R. § 814.39(d) 7

21 C.F.R. § 814.44 7

21 C.F.R. § 886.4392 8

INTRODUCTION

Nine years ago, this Court considered a petition for certiorari that raised the same question presented here: whether state-law damages claims concerning medical devices that received premarket approval ("PMA") from the Food and Drug Administration ("FDA") are preempted by the 1976 Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). *See Smith Industries Medical Systems, Inc. v. Kernats*, No. 96-1405, *cert. denied*, 522 U.S. 1044 (1998). Responding to the Court's request for advice on the petition, the Solicitor General agreed with the plaintiffs-respondents that PMA does not preempt state-law damages claims. *See* Brief of the United States As Amicus Curiae in *Kernats* at 14-18 (filed Dec. 1997). Although for reasons inapplicable here the Solicitor General recommended against granting certiorari in that case, he noted that "[t]he current division among the lower courts . . . would normally provide a strong justification for this Court to grant review and definitively resolve the conflict." *Id.* at 18.[1]

Today, the division among the lower courts, and thus the need for this Court's guidance, is even more pronounced than when the Solicitor General noted the conflict in his brief in *Kernats*. Today, an injured patient can maintain suit against the manufacturer of a PMA device in the courts of the Eleventh Circuit, for example, but not of the Second Circuit, and in Illinois state courts, for example, but not in Illinois federal

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[1]The Solicitor General argued that the petition should be denied because the Court did not have jurisdiction to review the state appellate court decision (which was not final under 28 U.S.C. § 1257), because the appellate court's holding that PMA did not preempt damages claims was correct, and because of the pendency of a proposed FDA interpretive rule (later withdrawn) regarding preemption.

courts. In fact, three circuit courts have reviewed the same FDA approval with respect to the same medical device, made by the same company, and reached two opposite conclusions. *Compare Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (no preemption of state-law damages claims), *with Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000) (preemption), and *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) (same). Because the courts' divergent analyses of the pre-emption question focus on the three opinions in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the conflict manifests not only a disagreement over the issue of PMA preemption, but also a disagreement about the obligation of lower courts to follow the holding of a majority opinion of this Court.

Adding to the confusion, the United States, in a letter brief filed in a Third Circuit case, *Horn v. Thoratec*, 376 F.3d 163 (3d Cir. 2004), reversed its position on preemption, making an argument that, by its own admission, contradicts the argument it made to this Court in *Kernats*. *See id.* at 177-78 (describing brief). The government's flip-flop heightens the already "strong justification for this Court to grant review and definitively resolve" the question presented.

In the past several years, this Court has denied review of petitions presenting substantially the same question presented here. *See, e.g., Knisley v. Medtronic*, 126 S. Ct. 420 (2005) (denying *cert.*); *Martin v. Medtronic*, 534 U.S. 1078 (2002) (same); *Brooks v. Howmedica*, 535 U.S. 1056 (2002) (same); *Kemp v. Medtronic*, 534 U.S. 818 (2001) (same); *Surgidev Corp. v Niehoff*, 523 U.S. 1005 (1998) (same). For the most part, opponents of review suggested that the courts that found no preemption might change their minds or be overturned en banc. That has not happened. The decisions finding no pre-emption—including the Eleventh Circuit's 1999 decision in

Goodlin v. Medtronic 167 F.2d 1367, the Tenth Circuit's 1997 decision in *Oja v. Howmedica*, 111 F.3d 782, the Illinois Supreme Court's 1999 decision in *Weiland v. Telectronics Pacing Systems*, 721 N.E.2d 1149, and the Kentucky Supreme Court's 1997 decision in *Niehoff v. Surgidev*, 950 S.W.2d 816—remain the law in those jurisdictions. Accordingly, it is now clear that the deep division among the lower courts is firmly established and will not be resolved without this Court's intervention.

OPINIONS BELOW

The decision of the United States Court of Appeals for the Second Circuit is not yet reported in F.3d and is reproduced in the Appendix at 1a. The district court's March 14, 2003 decision granting Respondent's motion for summary judgment in part is unreported and is reproduced in the Appendix at 55a. The district court's December 2, 2003 decision granting Respondent's subsequent summary judgment motion on the remaining claims is also unreported and is reproduced in the Appendix at 75a.

JURISDICTION

The judgment of the court of appeals was entered on May 16, 2006. Pet. App. 1a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

21 U.S.C. § 360k provides in part:

State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

> **(1)** which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> **(2)** which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 C.F.R. § 808.1(d) provides in part:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect

> devices that are not preempted by section 521(a) of the act [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. . . .

STATEMENT OF THE CASE

This petition arises from a state-law damages suit by Charles and Donna Riegel to recover for injuries suffered by Mr. Riegel from a balloon catheter manufactured by respondent Medtronic, Inc. The court of appeals held that the MDA preempts the Riegels' claims.

Because an understanding of the structure of the MDA is important to understanding this case, Part A below offers a general description of the MDA. Part B describes the decision in *Medtronic v. Lohr*, in which the Court considered the scope of the MDA's preemption provision. Part C sets forth the facts of this case and the proceedings below.

A. The Medical Device Amendments

Congress enacted the MDA principally to increase consumer protection by preventing the distribution of dangerous medical devices and by providing a process through which devices could reach the market. H.R. Rep. 853, 94th Cong., 2d Sess. 1-12 (1976); *see* P.L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. § 360c *et seq.*). Introducing the bill on the Senate floor, the bill's principal sponsor stated: "The legislation is written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. S6140 (Apr. 17, 1975) (Sen. Kennedy).

Under the MDA, each medical device falls into one of three classes. Class I devices, such as band-aids, are the least risky devices and are subject only to "general controls" applicable to all devices, such as general labeling requirements and good manufacturing practices rules promulgated by the FDA, the agency charged by Congress with implementing the MDA. *See* 21 U.S.C. § 360c(a)(1)(A).

Class II devices, such as hearing aids and tampons, are more likely than class I devices to cause harm if they are defective or misused. *Id.* § 360c(a)(1)(B). The FDA may therefore subject them to "special controls," such as the agency's specific warning language for tampon labeling. *See* 21 C.F.R. § 801.430(c), (d) & (e).

Class III devices—such as the devices at issue here and in *Lohr*—are those that, in general, cannot be marketed until the FDA has found that they present a reasonable assurance of safety and effectiveness. 21 U.S.C. § 360c(a)(1)(C). Marketing

permission granted through this process is known as pre-market approval, or PMA. *Id.* § 360e(b)(1)(A).[2]

Three components of the regulatory structure are relevant to this petition. First, when the FDA approves a manufacturer's PMA application, it does not conclude that the device is free of defect in design or labeling. The FDA does not generate the device's design or labeling, and it does not test or conduct studies of the device. Rather, a device's design and labeling originate with the device manufacturer, on whose data the FDA depends in acting on the PMA application. *See* 21 C.F.R. §§ 814.20, 814.44. When granting PMA, the FDA typically sends a form approval letter reminding the manufacturer of generally applicable obligations under federal regulations. There is nothing device-specific in the form approval letter. And although manufacturers of PMA devices must generally conform their products to the approved design and labeling that they devised, they may make design changes with FDA approval. *Id.* § 814.39(a). They may also make labeling changes to enhance safety, such as strengthening contra-indications and warnings, without pre-approval from the FDA. *Id.* §§ 814.39(d)(1) & (2).

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[2]If the FDA finds that a class III device is "substantially equivalent" to a device marketed prior to the MDA's effective date, or to a device that itself was found to be "substantially equivalent" to a pre-MDA device, that device need not obtain PMA until the FDA issues a regulation requiring PMA for that type of device. 21 U.S.C. §§ 360e(b)(1)(B), 360c(f)(1)(A). The FDA's process for giving marketing approval to such a device is sometimes referred to as the "510(k)" process, after the section of the FDCA under which the marketing request is submitted. *See Lohr*, 518 U.S. at 478.

Second, in a few instances, the FDA has issued device-specific requirements for particular types of devices. For instance, the FDA has issued design requirements for certain laser devices, *id.* § 886.4392, and absorbency testing requirements for tampons, *id.* §§ 801.420, 801.430(f). The FDA has never promulgated any such device-specific requirements for balloon catheters, such as the catheter that caused Mr. Riegel's injuries.

Third, the MDA contains a provision, 21 U.S.C. § 360k(a), that preempts certain state-law "requirements" "with respect to a device" that are "different from, or in addition to," MDA "requirements." Under section 360k(b), the FDA may exempt from preemption state requirements that would otherwise be preempted, and FDA regulations implementing this authority reflect section 360k(a)'s narrow reach. *See generally* 21 C.F.R. § 808.1; *see Lohr*, 518 U.S. at 498 n.18 ("FDA's narrow understanding of the scope of § 360k(a) is obvious from the full text of the regulation[.]"). For instance, FDA regulations provide that an FDA requirement has preemptive effect only when it establishes a device-specific "counterpart" to a "divergent" state-law requirement. 21 C.F.R. § 808.1(d). Likewise, to be preempted, state-law requirements must be "specific." Thus, preemption does not extend to state requirements of "general applicability where the purpose of the requirement relates . . . to other products in addition to devices." *Id.* § 808.1(d)(1).

Approximately 15 years after enactment of the MDA, device manufacturers began to argue that section 360k(a) preempts state damages actions. The legislative history of section 360k(a), however, refers solely to the potential for preemption of state and local laws and regulations. *See* H.R. Rep. No. 853 at 4, 45-46.

B. The Decision in *Medtronic v. Lohr*

In *Lohr*, plaintiff Lora Lohr and her husband Michael Lohr filed suit under Florida law for damages resulting from an allegedly defective class III pacemaker lead that the FDA had cleared for marketing under its section 510(k) "substantial equivalence" process. *See supra* note 2. This Court held that none of the Lohrs' claims—based on defective design, defective manufacture, and failure to warn—was preempted by the MDA.

1. *The Majority Opinion.* The majority opinion in *Medtronic* contains three holdings in which all members of the Court concurred: (1) The MDA does not broadly preempt all state-law damages claims against device manufacturers, *see Lohr*, 518 U.S. at 480 (majority); *id.* at 505 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); (2) the Lohrs' design-defect claim was not preempted because the FDA had not issued any design specifications for the device in question, *id.* at 492-94 (majority); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); and (3) a tort claim premised on state-law duties "equal to, or substantially identical to, requirements" imposed under the MDA or FDA regulations is not preempted. *Id.* at 494-97; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

By a 5-4 margin, in Part V of the *Lohr* majority opinion, the Court also held that the Lohrs' failure-to-warn and manufacturing-defect claims were not preempted, even if they did more than seek to enforce the federal requirements. The Court looked to the language of the MDA's preemption provision and the FDA's preemption regulations and noted the "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal

interest." *Id.* at 500. The generality of the FDA's labeling and manufacturing regulations applicable to the pacemaker lead, the Court held, precluded a finding of preemption. Those federal requirements, the Court said, reflect "important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* at 501.

The Court further noted that the Lohrs' damages claims were premised on general state-law duties that did not focus specifically on medical devices. Thus, the Court found that the general state-law duties to use due care in manufacturing and to warn users of potential risks are not the types of requirements that Congress or the FDA feared would impede the FDA's ability to enforce specific federal laws and regulations. Because they were based on general principles of state law, the majority held, such claims were outside of the prohibited category of state-law requirements "with respect to" specific devices within the meaning of section 360k(a). *Id.* at 501-02.[3]

2. *The Concurrence.* Justice Breyer filed a concurring opinion stating that, in his view, section 360k(a)'s reference to state-law "requirements" encompasses state-law damages claims. He did not join Parts IV and VI of the lead opinion (*see supra* note 3) because he was not convinced that MDA

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[3]Speaking for a four-Justice plurality, the lead opinion relied on the MDA's language and history to conclude that section 360k(a) was not intended to preempt most, and perhaps any, damages claims. 518 U.S. at 488-91. The plurality found it unnecessary to decide whether section 360k(a) reached any damages claims, however, because, under the majority's more focused analysis, none of the Lohrs' claims was preempted. *Id.* at 502-03.

preemption of damages claims would be "rare." *Id.* at 508. He joined fully, however, in Part V of the majority opinion, discussed immediately above, which demanded specificity on both the state and federal sides of section 360k(a)'s preemption analysis. He stated that the applicable FDA requirements that were related to the Lohrs' claims were not "specific" in any relevant sense and deferred to the FDA's preemption regulation, 21 C.F.R. § 808.1(d), which amplifies the meaning of section 360k(a)'s specificity requirement. 518 U.S. at 505-06. He noted that the language of section 360k(a) reflects principles of conflict preemption, but found no conflict between any federal requirement and any of the Lohrs' claims. *Id.* at 506.

3. *The Partial Dissent.* Justice O'Connor dissented in part and concurred in part, joined by Chief Justice Rehnquist and Justices Scalia and Thomas. In her view, state-law damages claims could constitute "requirements" under section 360k(a). *Id.* at 509-11. Although concurring with the majority that the Lohrs' design-defect claim was not preempted, she would have held that the manufacturing-defect and failure-to-warn claims were preempted to the extent that they sought to impose requirements different from those imposed by the FDA's manufacturing and labeling rules. *Id.* at 513-14. She agreed with the majority, however, that the Lohrs' manufacturing-defect and failure-to-warn claims were not preempted to the extent that they alleged violations of federal requirements. *Id.* at 513.

C. Factual Background and Proceedings Below

This action arose from serious injuries caused by a defective Medtronic balloon catheter. The catheter received marketing approval in 1994 as a supplement to a PMA first

issued in 1988. In 1995 and 1996, Medtronic sought and received approval to make design and labeling changes.

In May 1996, Charles Riegel underwent an angioplasty intended to dilate his coronary artery. His physician used the Medtronic catheter, which burst during the angioplasty. Mr. Riegel developed a complete heart block, and he lost consciousness and blood pressure. Advanced life support was needed to sustain him, and he was rushed to the operating room for emergency coronary bypass surgery. Pet. App. 4a.

The Riegels sued Medtronic, alleging design, labeling, and manufacturing defects and stating negligence, strict liability, and express and implied warranty claims. In January 2002, Medtronic moved for summary judgment based on preemption and to dismiss the express warranty claim for failure to state a claim. In March 2002, the district court granted the summary judgment motion in part, holding that all of the Riegels' claims are preempted except for those based on negligent manufacturing and express warranty. *See id.* at 55a. Following discovery, Medtronic moved for summary judgment on the two remaining claims; the district court granted the motion in a ruling no longer at issue. *Id.* at 75a.

The Riegels appealed the district court's decisions with respect to preemption and the manufacturing defect claim. In a 2-to-1 decision, the Second Circuit affirmed the district court. The majority held that PMA imposes device-specific preemptive "requirements" within the meaning of section 360k(a) and that the Riegels' design and labeling claims are sufficiently "device-specific" to warrant preemption. *Id.* at 25a, 30a. The majority suggested that jury verdicts put manufacturers of PMA devices in an untenable position because compliance with both federal requirements and jury verdicts

might be "impossible." *Id.* at 34a. The court did not attempt to reconcile that statement with the decades of jury verdicts in medical device cases or with this Court's recent decision in *Bates v. DowAgroSciences*, which noted that "an event, such as a jury verdict, that merely motivates an optional decision is not a requirement." 125 S. Ct. 1788, 1799 (2005); *see also Cipollone v. Liggett Group*, 505 U.S. 504, 518 (1992) ("[T]here is no general, inherent conflict between [express] federal preemption of state [regulatory] warning requirements and the continued vitality of state common-law damages actions."); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185-86 (1988) ("The effects of direct regulation . . . are significantly more intrusive than the incidental effects of such an award provision. . . . Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not.").

Judge Pooler dissented from the panel's preemption decision. Explaining that express preemption is a question of congressional intent, she noted the complete lack of evidence that Congress intended to preempt damages claims. Pet. App. 46a. She further observed that the idea that damages claims are "unambiguously preempted is 'particularly dubious' considering that it appears that until relatively recently neither the industry nor the FDA thought that such claims were preempted." *Id.* at 46a (citing *Bates*, 125 S. Ct. at 1801). Judge Pooler explained that the majority opinion overlooked "two critical aspects of the preemption analysis: the presumption against preemption and congressional intent," *id.* at 43a, both of which "weigh against a finding of preemption." *Id.* She also observed that "the lack of any device-specific federal requirement [for balloon catheters] makes it impossible" to conduct "a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state

requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." *Id.* at 50a (quoting *Lohr*, 518 U.S. at 500).

REASONS FOR GRANTING THE WRIT

A. The Federal And State Appellate Courts Are Deeply Divided Regarding The Application Of *Medtronic v. Lohr* To The Question Presented.

The decision and dissent below reflect the division among the federal and state appellate courts on the question presented: whether the FDA's grant of PMA for a medical device triggers preemption of state-law damages claims alleging that a manufacturer did not properly design the device and failed to warn of the device's risks. The split in authority is particularly problematic in Illinois, Kentucky, and Iowa, where, if the complaint is filed in or removed to federal court, the plaintiff's claims are expressly preempted, but if the complaint is litigated in state court, there is no preemption. *Compare Mitchell*, 126 F.3d 902 (7th Cir.), *Kemp*, 231 F.3d 216 (6th Cir.), *and Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001), *with Weiland*, 721 N.E.2d 1149 (Ill.), *Niehoff*, 950 S.W.2d 816 (Ky.), *and State ex rel Miller v. New Womyn, Inc.*, 679 N.W.2d 593 (Iowa 2004). Further displaying the division of views on the issue, the decision below and other recent appellate decisions finding preemption have provoked lengthy dissents. *See* Pet. App. 43a (Judge Pooler, dissenting from panel decision); *Horn*, 376 F.3d at 180 (in Third Circuit, Judge Fuentes, dissenting from panel decision); *Brooks v. Howmedica*, 273 F.3d at 799-801 (in Eighth Circuit, Judge Bye, joined by Judge Heaney, dissenting from en banc decision).

As noted above, *Lohr* requires that, before preemption may occur, both the allegedly preemptive federal requirement and the allegedly preempted state-law requirement must be "specific" within the meaning of section 360k(a) and regulations promulgated thereunder. *See* 21 C.F.R. § 808.1(d). As the decision below recognized, Pet App. 23a & n.16, conflicts among the federal and state appellate courts exist with respect to both prongs of *Lohr*'s analytic framework.

1. Looking first to the federal-law side of section 360k(a)'s preemption inquiry, *Lohr* held that, to have preemptive effect under 21 U.S.C. § 360k(a), a federal requirement must be specific. Thus, a specific labeling requirement for a particular type of device might have preemptive effect (*see, e.g.*, 21 C.F.R. § 801.430), in contrast to the comprehensive, but general labeling regulations that the Court held did not have preemptive effect. 518 U.S. at 497-99.

The FDA's criteria for PMA applications are general and do not require devices to be designed or labeled in any particular manner. Accordingly, several courts, including the Eleventh Circuit and the Illinois Supreme Court, have held that PMA does not impose device-specific requirements for purposes of preemption under section 360k(a). *See Goodlin*, 167 F.3d at 1373-77 (11th Cir.); *Weiland*, 721 N.E.2d at 1152-53 (Ill.); *Haidak v. Collagen Corp.*, 67 F. Supp. 2d 21, 23-24 (D. Mass. 1999); *Lakie v. SmithKline Beecham*, 965 F. Supp. 49 (D.D.C. 1997); *Quillen v. American Hosp. Supply Corp.*, 1997 U.S. Dist. Lexis 6974, *14-*15 (N.D. Okla. Mar. 31, 1997); *Sowell v. Bausch & Lomb*, 656 N.Y.S.2d 16, 20-21 (N.Y. App.

Div. 1997); *Walker v. Johnson & Johnson Vision Prods., Inc.*, 552 N.W. 2d 679, 684 (Mich. App. 1996).[4]

Other courts, including the Second Circuit below, have come to the opposite conclusion. *See, e.g.*, Pet. App. 25a; *Horn*, 376 F.3d at 169; *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998), *cert. denied*, 524 U.S. 954 (1998); *Fry*, 695 A.2d at 516; *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996), *cert. denied*, 520 U.S. 1168 (1997); *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 887-88 (Cal. App. 1997).

2. The split in authority is also profound on the state-law side of *Lohr*'s preemption analysis. The Fifth Circuit, for example, has simply ignored *Lohr*'s holding that damages claims are not preempted if they are premised on general state-law duties that do not focus specifically on medical devices. *See Martin*, 254 F.3d at 582-83. Other post-*Lohr* courts that have found damages claims preempted have dealt with the issue more directly, acknowledging *Lohr*'s majority holding and

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[4]Similarly, two state supreme courts have held that state-law damages claims involving class III devices marketed under the MDA's investigational device approval process (*see* 21 U.S.C. § 360j(g))—which is often a precursor to the PMA process—are not preempted because that process does not establish specific requirements under *Lohr*. *See Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) (en banc), *cert. dismissed*, 520 U.S. 1260 (1997); *Niehoff v. Surgidev*, 950 S.W.2d at 822. *But see Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095 (6th Cir. 1997) (investigational device process does establish preemptive federal requirements), *cert. denied*, 522 U.S. 1075 (1998). *See also Worthy*, 967 S.W.2d at 374 (noting conflict in appellate authority over preemptive effect of MDA's investigational device provisions and stating that PMA and investigational processes are comparable).

noting that it would, if applied in those cases, require a ruling in favor of the plaintiff. *See, e.g., Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. 1997). However, those courts, including the Second Circuit below, have refused to follow this portion of the majority opinion on the ground that it is purportedly incompatible with Justice Breyer's concurrence. *See* Pet. App. 21 n.14 & 30-31; *Horn*, 376 F.3d at 174-75; *Papike*, 107 F.3d at 742; *Mitchell*, 126 F.3d at 912; *see also Steele*, 63 Cal. Rptr. at 887; *Fry*, 695 A.2d at 517.

These rulings are at odds with the decisions of other appellate courts that have held that this Court's majority opinion in *Lohr* meant what it said: State laws of general applicability are not among those laws targeted for preemption by section 360k(a). *See Oja v. Howmedica*, 111 F.3d 782, 789 (10th Cir. 1997) (notwithstanding existence of specific federal label requirement applicable to the device, no preemption of labeling claim because "Howmedica's general duty to warn users of potential dangers in this case does not have 'the effect of establishing a substantive requirement for a specific device'"); *State ex rel Miller*, 679 N.W.2d at 596 (no preemption of claim against device manufacturer brought under state consumer fraud statute because statute not limited to devices); *Niehoff*, 950 S.W.2d at 822 (no preemption because "Kentucky's strict liability case law and statutes [on which plaintiff relies] are laws of general applicability to all products and fall beyond the scope of the federal preemption under § 360k"); *Walker*, 552 N.W.2d at 686; *Mears v. Marshall*, 944 P.2d 984, 993-95 (Ore. App. 1997), *review denied*, 961 P.2d 217 (Ore. 1998); *Wutzke v. Schwagler*, 940 P.2d 1386, 1391-92 (Wash. App. 1997), *review denied*, 953 P.2d 96 (Wash. 1998); *Baird v. American Med. Optics*, 693 A.2d 904, 909-10 (N.J. Super., App. Div.), *modified and remanded*, 713 A.2d 1019 (N.J. 1997); *Kernats v. Smith Indus. Med. Sys.*, 669 N.E.2d

1300, 1309 (Ill. App.) ("[P]laintiffs' claims emanate from general common-law duties and are not the sort of state requirements that section 360k was intended to preempt."), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *cert. denied*, 522 U.S. 1044 (1998); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771-72 (Cal. App. 1996), *review denied*, 1997 Cal. LEXIS 833 (Cal. 1997).

This Court should grant the petition to resolve these conflicts among the federal and state appellate courts.

3. Petitioners acknowledge that the decision below is consistent with the decisions of a majority of courts of appeals to have considered preemption of claims involving PMA devices. This point, however, does not lessen the need for this Court to resolve the persistent conflict. In fact, in a series of cases beginning in the early 1990s, this Court has disagreed with a majority of lower courts as to the effect of an express preemption provision on state-law damages claims. Most recently, in *Bates*, the Court rejected a pesticide manufacturer's sweeping preemption argument and the holdings of nine United States courts of appeals, based on a preemption provision "similarly worded" to section 360k(a). 125 S. Ct. at 1800. Likewise, in *Lohr*, the Court rejected the broad preemption holdings of a majority of the appellate courts that had considered the scope of express preemption under the MDA. *See* 518 U.S. at 492-502; *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 55 n.3, 63-64 (2002) (rejecting unanimous holdings of federal appellate courts on preemption under Boat Safety Act); *Geier v. American Honda Motor Co.*, 529 U.S. 861, 867-68 (2000) (rejecting holdings of a majority of federal appellate courts on express preemption under Motor Vehicle Safety Act); *Cipollone*, 505 U.S. 504 (rejecting broad preemption holdings of a majority of appellate courts and

finding only limited preemption of damages claims under Federal Cigarette Labeling and Advertising Act).

As these cases indicate, the lower courts have not gotten the message that express preemption provisions are to be narrowly construed. The courts' persistent failure to heed the principles set forth in this Court's recent preemption jurisprudence further demonstrates that the Court's guidance is urgently needed here.

B. The Second Circuit's Holding Cannot Be Reconciled With *Lohr*.

The decisions holding that PMA preempts damages claims are inconsistent with *Lohr* in three fundamental ways. First, the granting of PMA imposes no device-specific requirement triggering preemption of damages claims under section 360k(a). The PMA process is often more rigorous than the 510(k) marketing process at issue in *Lohr*, 518 U.S. at 478-79 (explaining differences), but it is no more "specific." Both processes apply to class III devices generally, and neither specifies how a product must be designed, manufactured, or labeled. As the Eleventh Circuit has explained, although the PMA process "differs in significant ways from the 510k process," the differences do not give rise to preemption under *Lohr*: "[B]ecause the [PMA] approval itself neither reveals nor imposes any ascertainable substantive prerequisite for approval that we could compare to a purportedly conflicting state requirement, the approval itself does not fit within section 360k(a)(1)'s demand for a specific federal requirement." *Goodlin*, 167 F.3d at 1374, 1376; *see id.* at 1376-77 (FDA's "conditions of [PMA] approval" are generic and thus not preemptive).

Thus, the PMA process embodies no rules similar to the FDA's device-specific labeling rules (*see, e.g.*, 21 C.F.R. § 801.420), or to the hypothetical FDA-required two-inch hearing aid wire discussed in Justice Breyer's *Lohr* concurrence. *Lohr*, 518 U.S. at 504. Moreover, the PMA process itself does not impose specific federal "requirements," as required by section 360k(a), 21 C.F.R. § 808.1(d), and *Lohr*, because the device's specifications originate with the manufacturer, not with the FDA. *Cf. American Airlines, Inc. v. Wolens*, 513 U.S. 219, 228-29 (1995) (preemption clause of Airline Deregulation Act does not shelter airlines from lawsuits "seeking recovery solely for the airline's alleged breach of its own, self-imposed undertakings").

Second, the decisions finding preemption of traditional damages claims involving PMA devices misapprehend *Lohr* because such claims are, without dispute, premised on state-law duties of general applicability. *See Lohr*, 518 U.S. at 501-02. The FDA's long-standing preemption regulation, 21 C.F.R. § 808.1, provides that section 360k(a) "does not preempt State or local requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to devices." 21 C.F.R. § 808.1(d)(1). The FDA's regulation encompasses the Riegels' traditional state-law claims, which are based on generally applicable tort duties. Notably, although the panel majority recognized that *Lohr* "relied upon 21 C.F.R. § 808.1(d)," Pet. App. 19a n.11, the panel failed to consider or apply the regulation.

Third, the court below, like several other courts of appeals, have held that PMA preempts traditional damages claims only by disregarding the *Lohr* majority's analysis and focusing on Justice Breyer's concurrence. *See, e.g.*, Pet. App. 22a n.14 ("There is, undeniably, a certain degree of tension

between Justice Breyer's joining of Part V of the opinion and his separate concurrence. We resolve that tension in favor of the latter."); *Horn*, 376 F.3d at 174-76; *Mitchell*, 126 F.3d at 912. However, even assuming that Justice Breyer's concurrence represents *Lohr*'s holding, the holdings of those courts are inconsistent with the concurrence. Justice Breyer explained that a specific federal regulation demanding a two-inch hearing aid wire would preempt a common-law claim premised on a specific state-law requirement for a one-inch wire. *Lohr*, 518 U.S. at 504 (Breyer, J., concurring). Yet damages claims such as the Riegels', which are based on general state-law duties to design a safe product and to warn of its risks do not involve a specific state-law requirement of this kind. Moreover, they have no counterpart in specific federal requirements. Thus, such claims do not present the kind of direct conflict that concerned Justice Breyer.

More fundamentally, even if the concurrence could be read to favor preemption of generally applicable state-law duties, a lower court has no authority to disregard a majority holding of this Court. Federal courts of appeals are bound to adhere to the controlling decisions of the Supreme Court. *See Hutto v. Davis*, 454 U.S. 370, 375 (1982) ("[U]nless we wish anarchy to prevail within the federal judicial system, a precedent of this Court must be followed by the lower federal courts no matter how misguided the judges of those courts may think it to be."). A separate concurrence, regardless of its content, is not a basis for disregarding a majority opinion of the Supreme Court of the United States. *See Alexander v. Sandoval*, 532 U.S. 275, 285 n.5 (2001) (concurrence does not alter meaning of majority opinion); *Maryland v. Wilson*, 519 U.S. 408, 413 (1997) (concurring opinion does not establish precedent); *see also Agostini v. Felton*, 521 U.S. 203, 217 (1997) (case law not affected by views of five Justices in

concurring opinions). As the Tenth Circuit recognized in *Oja*, 111 F.3d at 788 n.3, the five-justice majority opinion is the binding precedent established in *Lohr*. The appellate courts' misapplication of rules of precedent underscores the need for review here.

C. The Decision Below Leaves Patients Injured By The Most Risky Devices With No Remedy—A Result Inconsistent With The History Of The MDA.

Review should also be granted because the Second Circuit's and other courts' misinterpretation of *Lohr* and section 360k(a) leaves consumers injured by PMA devices without any remedy in many parts of the country. Where, as here, the federal regulatory scheme does not itself provide a damages remedy, this Court has ascribed preemptive intent to Congress only in the most compelling circumstances. *See English v. General Elec. Co.*, 496 U.S. 72, 87-90 (1990); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) ("perfectly rational for Congress not to pre-empt common-law claims" when preempting state regulatory law because common-law claims "perform an important remedial role in compensating accident victims"). Such circumstances are not present here.

Congress, when enacting the MDA, made no mention of a desire to preempt common-law claims. Pet. App. 45a-46a (dissent); *see also Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("Congress would [not], without comment, remove all means of judicial recourse for those injured by illegal conduct."). Congress' silence on this point is particularly telling because a major impetus for the MDA was the highly publicized injuries caused by the Dalkon Shield

intrauterine device, which resulted in "well-known, ongoing litigation." Pet. App. 45a (dissent); *Goodlin*, 167 F.3d at 1378 (citing *Lohr*, 518 U.S. at 475-77); *Lohr*, 518 U.S. at 491 (plurality) (Congress was "acutely aware of ongoing product liability litigation" regarding Dalkon Shield). In crafting the MDA, Congress focused on "regulat[ing] medical devices *before* they reached consumers, rather than on addressing their consequences once on the market." *Goodlin*, 167 F.3d at 1378 (emphasis in original). "It would have been inconsistent for the same Congress that enacted these sweeping reforms, intending to make a potentially dangerous industry safer for patients by blocking the admission of defective devices to the market, then to preempt product liability suits when those devices caused injury." *Id.*

Moreover, the notion that section 360k(a) unambiguously preempts state damages claims "is 'particularly dubious' considering it appears that until relatively recently neither the industry nor the FDA thought such claims were preempted." Pet. App. 46a (dissent) (quoting *Bates*, 125 S. Ct. at 1801). More specifically, in 1997, 20 years after enactment of the MDA, the FDA argued to this Court that claims such as the Riegels' were not preempted. *See supra* p.1; *Bates*, 125 S. Ct. at 1801 ("The notion that FIFRA contains a nonambiguous command to pre-empt the types of tort claims that parallel FIFRA's misbranding requirements is particularly dubious given that just five years ago the United States advocated the interpretation that we adopt today."). And the first reported decisions on the medical device industry's attempts to argue that section 360k(a) preempts product liability claims are from 1991, 15 years after enactment. Pet. App. 47a (dissent); *Goodlin*, 167 F.3d at 1381. The notion "that the industry would have ignored its immunity under the MDA for so long after the statute's enactment if Congress, in fact, had intended to provide

immunity in 1976" is far-fetched, *id.*, and further shows the Second Circuit's misunderstanding of the scope of section 360k(a).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2005

Argued: December 15, 2005 Decided: May 16, 2006
Errata Filed: July 20, 2006

Docket No. 04-0412-cv

CHARLES R. RIEGEL AND DONNA S. RIEGEL,
Plaintiffs-Appellants,

—v.—

MEDTRONIC, INC.,
Defendant-Appellee.

Before:
POOLER, KATZMANN, AND B.D. PARKER, *Circuit Judges*

Appeal from a judgment of the United States District Court for the Northern District of New York (Kahn, *J.*) granting the defendant's motion for summary judgment. Affirmed.

Judge Pooler concurs in part and dissents in part in a separate opinion.

KATZMANN, *Circuit Judge*:

This case calls upon us to determine, *inter alia*, the scope of the preemption provision set forth in Section 360k(a) of the

1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et. seq.* Specifically, we must decide whether Section 360k(a) preempts common law tort claims regarding medical devices that have entered the market pursuant to the Food and Drug Administration's ("FDA") rigorous premarket approval ("PMA") process. The Supreme Court left open this question in *Medtronic v. Lohr*, 518 U.S. 470 (1996), which held that tort claims as to medical devices that have entered the market pursuant to the far less intensive premarket notification process (often referred to as the "Section 510(k) process") are not preempted by Section 360(k)(a). Since *Lohr*, the majority of circuits addressing this question have held that claims regarding PMA-approved medical devices are, by contrast, preempted. *See Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997); *but see Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999).

We now join this growing consensus and hold that tort claims that allege liability as to a PMA-approved medical device, notwithstanding that device's adherence to the standards upon which it obtained premarket approval from the FDA, are preempted by Section 360(k)(a). We therefore affirm the district court's (Kahn, *J.*) summary judgment dismissal of the plaintiffs-appellants' strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, and sale claims as to the Evergreen Balloon Catheter, a PMA-approved medical device. With regard to the plaintiffs' remaining claim for negligent manufacturing – which premised liability on the theory that the particular Evergreen Balloon Catheter deployed during plaintiff-appellant Charles Riegel's angioplasty had not been

manufactured in accordance with the PMA-approved standards – we agree with the district court that this claim was not preempted, but that no genuine issue of material fact existed, and thus affirm the district court's summary judgment dismissal of that claim as well.

We note that our preemption analysis is quite limited in scope, affecting the small universe of cases resting on claims alleging liability despite a PMA-approved device's adherence to the standards upon which it secured FDA premarket approval. We take care to explain that we do not hold that all state tort claims as to PMA-approved devices are preempted. Thus, tort claims that are based on a manufacturer's departure from the standards set forth in the device's approved PMA application – such as the Riegels' negligent manufacturing claim – are not preempted.

I.

A.

The Evergreen Balloon Catheter is a prescription medical device that defendant-appellee Medtronic, Inc. developed for patients with coronary disease. Physicians use it during angioplasties to open patients' clogged arteries, essentially by inserting the catheter into the clogged vessel, inflating the catheter like a balloon, and then deflating and removing the catheter. The Evergreen Balloon Catheter entered the market pursuant to the PMA process in the mid1990s. Specifically, on August 30, 1994, the FDA approved Medtronic's PMA application for the Evergreen Balloon Catheter, and on April 27, 1995 and April 18, 1996, the FDA approved Medtronic's PMA supplements, which requested approval for revised

labeling for the device. We discuss the PMA process in greater depth *infra* Part III.A.

On May 10, 1996, plaintiff-appellant Charles Riegel underwent a percutaneous transluminal coronary angioplasty, during which his surgeon used an Evergreen Balloon Catheter. The procedure was intended to dilate Riegel's right coronary artery, which had been found to be "diffusely diseased" and "heavily calcified." The device label for the Evergreen Balloon Catheter specifies that its use is contraindicated for patients who have "diffuse or calcified stenoses." During the procedure, Riegel's physician, Dr. Eric Roccario, first attempted to remove the calcium deposits in Riegel's artery with a rotoblator device, and then unsuccessfully inserted several different balloon catheters. Dr. Roccario ultimately inserted the Evergreen Balloon Catheter into Riegel's artery and inflated the device several times, up to a pressure of ten atmospheres. The device label for the Evergreen Balloon Catheter specifies that it should not be inflated beyond the "rated burst pressure" of eight atmospheres. On the final inflation, the Evergreen Balloon Catheter burst, and Riegel began to rapidly deteriorate. He developed a complete heart block, lost consciousness, was intubated and placed on advanced life support, and was rushed to the operating room for emergency coronary bypass surgery. Riegel survived, but according to his Complaint, he suffered "severe and permanent personal injuries and disabilities."

B.

Riegel and his wife, Donna, subsequently filed suit against Medtronic in the Northern District of New York, alleging five state common law causes of action: (1) negligence in the design, testing, inspection, manufacture, distribution, labeling,

marketing, and sale of the Evergreen Balloon Catheter; (2) strict liability; (3) breach of express warranty; (4) breach of implied warranty; and (5) loss of consortium.[1] In its amended answer, Medtronic raised the affirmative defense of federal preemption by Section 360k(a) of the 1976 Medical Device Amendments, 21 U.S.C. § 360(c)-(k), to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et. seq,* and subsequently moved for summary judgment on its preemption defense.

In a March 14, 2002 opinion, the district court (Kahn, *J.*) ruled that the Riegels' strict liability claim, breach of implied warranty claim, and all of their negligence claims except for the negligent manufacturing claim were preempted by Section 360k(a), and therefore dismissed all of these claims. The court let stand the Riegels' breach of express warranty claim. Thus, discovery continued on the two remaining substantive claims: the negligent manufacturing claim and the breach of express warranty claim.[2]

Medtronic later moved for summary judgment on these two remaining claims, and on December 2, 2003, the district court granted that motion. The court dismissed the breach of express warranty claim because the Evergreen Balloon Catheter's instructions had clearly disclaimed any express warranty. It dismissed the negligent manufacturing claim on grounds that there was insufficient evidence upon which a reasonable fact-finder could conclude that the Evergreen Balloon Catheter had burst because of negligent manufacture, rather than because

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[1]Because the Riegels are residents of New York State, and Medtronic is a Minnesota corporation, the district court had diversity jurisdiction pursuant to 28 U.S.C. § 1332.

[2]The loss of consortium claim, a derivative claim, was permitted to remain in connection with the two remaining substantive claims.

it had encountered a calcium spicule in Riegel's artery, had been inflated beyond the specified eight atmosphere limit, or some combination thereof.

The Riegels proceeded to file the instant appeal, in which they challenge both the March 14, 2002 and December 2, 2003 summary judgment rulings of the district court. With regard to the March 14, 2002 ruling, they argue that none of their claims was preempted. With regard to the December 2, 2003 ruling, they argue that there were genuine issues of material fact as to their negligent manufacturing claim.[3]

II.

Initially, we note the applicable standard of review. An order granting summary judgment will be affirmed only when no genuine issue of material fact exists and the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *Island Software & Computer Serv. v. Microsoft Corp.*, 413 F.3d 257, 260 (2d Cir. 2005). With regard to the March 14, 2002 dismissal of many of the Riegels' claims on preemption grounds, there are no disputed facts, and "our task is to determine whether the district court correctly applied the law." *Pagan v. NYNEX Pension Plan*, 52 F.3d 438, 441 (2d Cir. 1995) (internal quotation marks omitted). With regard to the December 2, 2003 dismissal of the Riegels' negligent manufacturing claim, we must decide whether, "construing the evidence in the light most favorable to the non-moving party and drawing all reasonable inferences in its favor," there are any genuine issues of material fact. *SCS Communications, Inc. v. The Herrick Co., Inc.*, 360 F.3d 329, 338 (2d Cir. 2004).

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[3]The Riegels do not, however, challenge the summary judgment dismissal of their breach of express warranty claim.

III.

A.

We begin with the preemption issue, for which, at the outset, it is helpful to review the overarching regulatory structure. In 1976, Congress enacted the Medical Device Amendments ("MDA") to the 1938 Food, Drug, and Cosmetic Act, in order to "provide for the safety and effectiveness of medical devices intended for human use." 90 Stat. 539. The MDA established a regulatory structure pursuant to which the Department of Health and Human Services, through the FDA, would regulate medical devices.

Under the MDA, medical devices are categorized into three classes, based on the level of risk that they pose. 21 U.S.C. § 360c(a)(1). First, those devices that "present minimal potential for harm to the user," such as elastic bandages, are classified as "Class I" devices; such devices can be marketed without prior approval and are subject only to "general controls" that cover all medical devices. 21 U.S.C. § 360c(a)(1)(A); *see also* http://fda.gov/cdrh/devadvice/ 3132.html (last visited April 28, 2006); *Lohr*, 518 U.S. at 477. Second, devices that are potentially more harmful, such as powered wheelchairs and infusion pumps, are classified as "Class II" devices." These devices can still be marketed without advance approval, but in addition to being subject to "general controls," they may also be subject to "special controls," such as postmarket surveillance, patient registries, and/or other measures deemed necessary. 21 U.S.C. § 360c(a)(1)(B); *see also* http://fda.gov/ cdrh/devadvice/ 3132.html; *Lohr*, 518 U.S. at 477. Finally, those devices for which "general controls" and "special controls" are insufficient to provide reasonable assurance of safety and effectiveness, and which either "present a potential unreasonable risk of illness or injury" or are "for a use in

supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" are classified as Class III devices. 21 U.S.C. § 360c(a)(1)(C). It is undisputed that the Evergreen Balloon Catheter – the device at issue in this litigation – is a Class III device.[4]

A Class III device is required to undergo "premarket approval to provide reasonable assurance of its safety and effectiveness" before being marketed. 21 U.S.C. § 360c(a)(1)(C). The premarket approval, or "PMA," process is lengthy and rigorous. *See Lohr*, 518 U.S. at 477 (describing the PMA process as a "rigorous one," and noting that the FDA spends an average of 1,200 hours on each PMA submission). The manufacturer must submit a detailed PMA application that contains full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information. 21 U.S.C. § 360e(c).

There is significant opportunity for interaction between the FDA and the manufacturer over the course of the PMA process. Typically, the initial PMA application must include data from clinical investigations to establish the safety and effectiveness of the device, 21 C.F.R. § 814.20(b)(6)(ii); the manufacturer cannot even conduct such a clinical investigation in the first place without FDA permission, 21 C.F.R. § 812.1(a). The

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[4]Other examples of Class III devices include replacement heart valves and implanted cerebella stimulators. *See* http://fda.gov/cdrh/dev advice/3132.html.

results of such clinical investigations, in turn, must be included by the manufacturer in the PMA application, along with all of the information described above. *See* 21 C.F.R. § 814.20; 21 U.S.C. § 360e(c). The FDA then reviews the submission to determine whether it is sufficiently complete to enable a substantive review; if not, the FDA will refuse to file it. 21 C.F.R. § 814.42. After having accepted the PMA for filing, the FDA begins its review, which may involve referring the PMA to an advisory committee. 21 C.F.R. § 814.44; *see also* www.fda.gov/cdrh/devadvice/pma ("Review Process: Overview") (last visited April 28, 2006). On the 100th day after the PMA has been filed, the FDA will, at the applicant's request, meet with the applicant to discuss the status of the application and any deficiencies that need to be addressed. *See* 21 U.S.C. § 360e(d)(3).

Once the FDA has concluded its review, it decides whether or not to approve the device for marketing. This choice is not binary; the FDA has means to impose additional requirements. For example, the FDA can issue an "approvable letter" stating that the FDA believes it will be able to approve the application if specific conditions are agreed to by the applicant. *See* 21 C.F.R. § 814.44(e). Alternatively, if the FDA "believes that the application may not be approved," it can "send the applicant a not approvable letter...[that] will describe the deficiencies in the application...and, where practical, will identify measures required to place the PMA in approvable form." 21 C.F.R. § 814.44(f). The FDA thus has quite broad authority to approve, deny, and effectuate modifications of an application throughout the PMA process.

In the end, once the FDA has approved a medical device through the PMA process, the applicant is required to comply with the standards in the PMA approval order. 21 C.F.R.

§ 814.80 ("A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."). Any changes that the applicant believes could affect the safety or effectiveness of the device must be submitted, via a "PMA supplement," to the FDA for approval. 21 C.F.R. § 814.39(a) ("After FDA's approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA. . . .While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device: (1) New indications for use of the device[;] (2) Labeling changes[;] (3) The use of a different facility or establishment to manufacture, process, or package the device[;] (4) Changes in sterilization procedures; (5) Changes in packaging[;] (6) Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device[;] (7) Extension of the expiration date of the device. . . .").

Additionally, the standard FDA "Conditions of Approval" accompanying a PMA order state that continued approval of the PMA "is contingent on the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA." *See* www.fda.gov/devadvice/pma ("Postapproval (Annual) Reports") (last visited April 28, 2006). Such annual reports must (1) identify all changes made to the device (even if those changes did not affect the device's safety or effectiveness and therefore did not first require submission of a PMA supplement), 21 C.F.R. § 814(b)(1); (2) contain a summary and

bibliography of any "unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant," 21 C.F.R. § 814(b)(2)(i); and (3) contain a summary and bibliography of any "reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant," 21 C.F.R. § 814(b)(2)(ii). The standard PMA "Conditions of Approval" also require the manufacturer to submit an "Adverse Reaction Report" or "Device Defect Report" to the FDA within ten days after it receives or has knowledge of information concerning (1) "a mixup of the device or its labeling with another article"; (2) "any adverse reaction attributable to the device that has not been addressed by the device's labeling or is occurring with unexpected severity or frequency"; or (3) "any significant chemical, or other change or deterioration in the device or any failure of the device to meet the specifications established in the PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling." *See* www.fda.gov/devadvice/pma ("Adverse Reaction and Device Defect Reporting").[5] The FDA may also impose other requirements on manufacturers as a condition of PMA

[5]Manufacturers of PMA-approved devices are also fully subject to the FDA's general Medical Device Reporting Regulation, 21 C.F.R. § 803 *et. seq.*, which requires all manufacturers of medical devices to report to the FDA within 30 days of learning from any source that one of their devices "(1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and this device or a similar device that [it] market[s] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50. In the event that a manufacturer learns that a reportable event "necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health," it is required to submit a report to the FDA within five days. 21 C.F.R. § 803.53.

approval, such as restrictions on the sale or distribution of the device; continuing evaluation; prominent display of warnings; maintenance of records according to specifications deemed necessary by the FDA; batch testing; and any other requirements that the FDA "determines are necessary to provide reasonable assurance, or continued reasonable assurance, of the safety and effectiveness of the device." 21 C.F.R. § 814.82(a). The FDA can impose such requirements either in the initial PMA approval order, by regulation at the time of PMA approval, or by regulation subsequent to approval. *Id.*

The vast majority of Class III medical devices, however, reach the market without ever going through the rigorous PMA process described above. This is because the MDA also includes a "grandfathering" provision that "allows pre-1976 devices to remain on the market without FDA approval until such time as the FDA initiates and completes the requisite PMA." *Lohr*, 518 U.S. at 478. And, in order to "prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market," the MDA also allows new devices that are "substantially equivalent" to such pre-existing devices to enter the market without going through the PMA process. *Id.* This "substantial equivalence" route to the market is known as the premarket notification, or "§ 510(k)," process.[6]

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[6]The "§ 510(k)" reference stems from the number of the section in the original Act. *See Lohr*, 518 U.S. at 478. In addition to covering devices that are substantially equivalent to pre-1976 devices, the § 510(k) process also covers devices that are substantially equivalent to other devices not subject to the PMA process, *e.g.*, because those devices were reclassified from Class III to Class I or II. *See* http://www.fda.gov/cdrh/devadvice/314.html (last visited April 28, 2006).

In its decision, the *Lohr* Court noted that the § 510(k) premarket notification process has become the means by which most new medical devices enter the market. *Id.* at 479. This observation holds true with full force today. Indeed, from the FDA's website, it appears that in the fiscal year 2005, out of the 3,180 new Class III devices that were permitted to enter the market through either the § 510(k) or PMA processes, 3,148 of them went through the § 510(k) process and only 32 went through the PMA process.[7] In other words, in 2005, approximately ninety-nine percent of such devices went through the § 510(k) process and only *one percent* went through the PMA process.

As the contrasting terms "premarket notification" and "premarket approval" suggest, the § 510(k) process differs dramatically from the PMA process. Unlike the PMA process – which requires reasonable assurance that the new device is itself safe and effective, and ultimately results in the FDA's "approval" of the device – the § 510(k) process simply requires the manufacturer to show that the device is substantially equivalent to, *i.e.*, as safe and effective as, a legally marketed device that did not go through the PMA process. As the Supreme Court stated in *Lohr*, the § 510(k) process was apparently intended simply to "maintain the status quo with

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[7]The FDA's website provides monthly listings of all of the § 510(k)-cleared devices, *see* http://www.fda.gov/cdrh/510khome.html #listing (last visited April 28, 2006) and all of the PMA-approved original devices and supplements, *see* http://www.fda.gov/cdrh/pmapage.html# monthly (last visited April 28, 2006). These webpages, along with related information about recent device approvals by the FDA, can also be accessed via the webpage on the FDA's website entitled "Recent Device Approvals." *See* http://www.fda.gov/cdrh/consumer/mda/ ("Recent Device Approvals") (last visited April 28, 2006). The above numbers were calculated with reference to the website's 2005 monthly listings of § 510(k)-cleared devices and PMA-approved original devices.

respect to the marketing of existing medical devices and their substantial equivalents." *Lohr*, 518 U.S. at 494. To that end, "[t]he § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours." *Id.* at 478-79; *see also Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001) ("[T]he § 510(k) process lacks the PMA review's rigor: The former requires only a showing of substantial equivalence to a predicate device, while the latter involves a time-consuming inquiry into the risks and efficacy of each device.").

In fact, the FDA regulations explicitly prohibit manufacturers of devices that have reached the market through the § 510(k) process from indicating that the FDA has actually approved their device on the merits, stating that the § 510(k) determination that a device is "substantially equivalent" to a pre-existing, non-PMA-approved device on the market "*does not in any way denote approval of the device.* Any representation that creates an impression of a official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding." 21 C.F.R. § 807.97 (emphasis added).

Once a device has entered the market pursuant to the § 510(k) process, its manufacturer has broader latitude to make changes on its own than does the manufacturer of a PMA-approved device. As the FDA explained in its Amicus Curiae Letter Brief to the Third Circuit in *Horn v. Thoratec*, "[i]n direct contrast to the PMA regime, FDA does not 'approve' changes to a Section 510(k)-cleared device. Rather, the manufacturer simply has to demonstrate that its device is still substantially equivalent to its predicate." *Horn v. Thoratec Corp.*, 376 F.3d 163, 172 (3d Cir. 2004). To that end, whereas

a PMA supplement must be submitted for review and approval by the FDA before *any* change is made that "affect[s] the safety or effectiveness of the device," a § 510(k) supplemental submission is required only where the device "is about to be *significantly* changed or modified in design, components, method of manufacturer, or intended use," 21 C.F.R. § 807.81(a)(3) (emphasis added).[8]

Having summarized the PMA and § 510(k) routes to market set forth by the MDA, we now move to one final aspect of the MDA that is crucial for purposes of this case. The MDA also includes an express preemption provision: Section 360k(a). In relevant part, this provision states as follows:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

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[8]As examples of such "significant changes or modifications," the FDA listed a "change or modification in the device that could *significantly* affect the safety or effectiveness of the device," and a "*major* change or modification in the intended use of the device." 21 C.F.R. § 807.81(3)(i)-(ii) (emphasis added).

21 U.S.C. § 360k(a).[9]

The application of Section 360k(a)'s preemption provision to medical devices that have entered the market through the two alternate routes described above – the PMA process and the § 510(k) process – forms the crux of this case.

B.

During the several decades following the 1976 enactment of the MDA, the circuit courts grappled with how broadly to construe Section 360k(a)'s preemption of state "requirement[s]" that differed from or added to "requirement[s] applicable under this Act." Could a state requirement be created by state common law, or only by state statutes and other enactments? For that matter, did approval under the PMA process – or, alternatively, clearance under the § 510(k) process or some other expedited process – amount to a requirement under the Food, Drug, and Cosmetic Act with which state law could conflict?

This Court addressed some of these questions in *Becker v. Optical Radiation Corp*, 66 F.3d 18 (2d Cir. 1995). There, we stated that state common law claims that alleged product defects as to a PMA-approved device, notwithstanding that device's compliance with the PMA process, would be preempted by Section 360k(a). We explained:

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[9]The MDA goes on to provide, in Section 360k(b), that "[u]pon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a)" certain State regulations from the preemption provision. 21 U.S.C. § 360k(b). Neither party has argued that Section 360k(b) is applicable here.

> At the premarket stage, pursuant to the MDA, the FDA reviews a device's testing, design specifications, intended use, manufacturing method, performance standards and labeling, and decides whether the device is safe and effective. 21 U.S.C. §§ 360e(c)(1), (2). [The plaintiff's] claims allege defective design, defective manufacture, failure to warn and failure to test. If [the plaintiff] were allowed to pursue these claims, and if she were successful, the common law of New York would impermissibly add requirements in the areas reviewed in the [PMA] process, and thus would impose standards on the [device] which are different from those of the MDA.

Id. at 20. The *Becker* Court was not, however, presented with the question of whether common law claims as to § 510(k)-cleared devices would be similarly preempted.

It was this latter question that the Supreme Court considered in *Lohr*, where the plaintiffs brought various state tort law claims in regard to the design, manufacturing, and labeling of a pacemaker that had entered the market pursuant to the § 510(k) process. In the course of assessing whether these plaintiffs' tort law claims would – if successful – result in a state law "requirement" that differed from, or added to, a federal "requirement," a fractured Court reached several conclusions.

All nine justices agreed that the § 510(k) process set forth *no* federal requirements as to the design of medical devices, and that clearance through the § 510(k) process simply reflected the FDA's conclusion that a new device was substantially equivalent to a pre-existing device. Thus, the justices unanimously agreed that design defect claims as to

§ 510(k)-cleared devices would not be preempted by Section 360k(a) of the MDA because there would be no federal requirements with which such claims could conflict. *See Lohr*, 518 U.S. at 493-94 (majority opinion) (stating that clearance via the § 510(k) process "did not 'require' Medtronics' pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to the one that existed before 1976, to be marketed without running the gauntlet of the PMA process"); 518 U.S. at 513 (O'Connor, *J.*, concurring in part and dissenting in part) ("I agree with the Court that the Lohrs' defective design claim is not preempted by the FDCA's § 510(k) 'substantial equivalency' process....Because the § 510(k) process seeks merely to establish whether a pre-1976 and a post-1976 device are equivalent, and places no 'requirements' on a device, the Lohrs' defective design claim is not preempted.").[10]

When the justices moved from a consideration of the plaintiffs' design defect claims to their manufacturing and labeling claims, however, they fractured over two issues regarding the interpretation of Section 360k(a)'s preemption of state "requirements" that were "different from, or in addition to, any requirement applicable under this Act." First, the justices diverged over whether the reference to "requirements applicable under this Act" meant that only *device-specific* requirements could give rise to preemption, or instead meant that any FDA requirements could give rise to preemption. Five of the justices – Justices Stevens, Kennedy, Souter, Ginsburg, and Breyer – concluded that only federal device-specific

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[10]Justice O'Connor was joined by Chief Justice Rehnquist, Justice Scalia, and Justice Thomas.

requirements could give rise to preemption.[11] *Id.* at 497-500 (majority opinion); *id.* at 505-07 (Breyer, *J.*, concurring in part and concurring in the judgment). These justices therefore agreed that because the only FDA manufacturing and labeling requirements[12] that covered the pacemaker at issue were general in nature rather than device-specific, the plaintiffs' manufacturing and labeling claims were not preempted. By contrast, the remaining four justices – Justices Rehnquist, O'Connor, Scalia, and Thomas – concluded that even general FDA requirements could give rise to preemption, and therefore dissented, in part, on grounds that the plaintiffs' manufacturing and labeling tort claims as to the pacemaker were preempted by the general FDA manufacturing and labeling requirements. *Id.* at 511-514 (O'Connor, *J.*, concurring in part and dissenting in part).

In addition to their 5-4 split over whether the applicable federal requirement needed to be device-specific, the justices

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[11]In reaching this conclusion, they relied upon 21 C.F.R. § 808.1(d), an FDA regulation stating that "[s]tate and local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device difference [sic] from, or in addition to, the specific Food and Drug Administration requirements."

[12]The relevant labeling regulations were set forth in 21 C.F.R. § 801.109(b) and (c), pursuant to which manufacturers of medical devices must include labeling that "bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely. . . ." The relevant manufacturing regulations were set forth in the "Good Manufacturing Practices," or "GMP's," which are set forth in 32 sections of the Code of Federal Regulations. *See Lohr*, 518 U.S. at 497.

also divided – again by a 5-4 margin – over whether a state "requirement," as that term was used in Section 360k(a), could derive from state common law or only from state statutes and regulations. Justices Stevens, Kennedy, Souter, and Ginsburg largely adopted the view that only the latter category would typically give rise to a state requirement for purposes of the MDA, stating in Part IV of the opinion that "when Congress enacted § 360k, it was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions," *id.* at 489 (plurality opinion), and subsequently stating in part VI of the opinion that "it is apparent that few, if any, common law duties have been preempted by this statute. It will be rare indeed for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device,'" *id.* at 502-03 (plurality opinion).

Justice Breyer, however, declined to join Parts IV and VI of the opinion, and wrote separately to emphasize that he was "not convinced that future incidents of MDA preemption of common-law claims will be 'few' or 'rare.'" *Id.* at 508 (Breyer, *J.*, concurring in part and concurring in the judgment). He stated, with reference to the Court's prior holding in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992),[13] that "[o]ne can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law." *Id.* at 504. Justice Breyer further illustrated this point with the following hypothetical situation:

> Imagine that, in respect to a particular hearing aid component, a federal MDA regulation requires a 2-inch

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[13]The *Cipollone* decision is discussed in greater depth *infra*.

> wire, but a state agency regulation requires a 1-inch wire. If the federal law, embodied in the "2-inch" MDA regulation, pre-empts the state "1-inch" agency regulation, why would it not similarly pre-empt a state-law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that use of more than 1-inch wire is negligent)? The effects of the state agency regulation and the state tort suit are identical....Consequently, I believe that ordinarily, insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action.

Id. at 504-05. Finally, Justices Rehnquist, O'Connor, Scalia, and Thomas also adopted the view that, pursuant to *Cipollone*, "[i]f § 360(k)'s [sic] language is given its ordinary meaning, it clearly preempts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA – just as it would preempt a state statute or regulation that had that effect." *Id.* at 511 (O'Connor, *J.*, concurring in part and dissenting in part). In sum, therefore, five justices endorsed the proposition that a state "requirement," for purposes of the MDA, could stem from state common-law actions as well as from state statutes or regulations.[14]

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[14]We note that although Justice Breyer authored a separate concurrence as to this point, and declined to join Parts IV and VI of the *Lohr* opinion, he did join Part V of the *Lohr* opinion, which included the statements that "the general state common-law requirements in this suit were not specifically developed 'with respect to' medical devices," but would

We thus interpret *Lohr* as setting forth two main principles, each endorsed by five justices, for determining whether a common law tort action over a medical device is preempted by the MDA. First, on the federal side of the analysis, courts must consider whether there are any device-specific federal requirements with respect to the device at hand. If so, courts must then turn to the state side to determine whether there would be a conflict between that device specific federal requirement and "any of the liability-creating premises of the plaintiffs' state-law tort suit." *Lohr*, 518 U.S. at 508 (Breyer, *J.*, concurring in part and concurring in the judgment).

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simply stem from "general state common-law requirements," such as "the general duty of every manufacturer to use due care to avoid foreseeable danger in its products," and that "[t]hese state requirements therefore escape preemption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices . . . ." *Id.* at 501-02.

There is, undeniably, a certain degree of tension between Justice Breyer's joining of Part V of the opinion and his separate concurrence. We resolve that tension in favor of the latter. Given that Justice Breyer wrote separately to assert that "the MDA will sometimes preempt a state-law tort suit," *id.* at 503 (Breyer, *J.*, concurring in part and concurring in the judgment), that he was "not convinced that future incidents of MDA pre-emption of common-law claims will be 'few' or rare,'" *id.* at 508, that "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action," *id.* at 504-05, and – most explicitly – that he "basically agree[d] with Justice O'Connor's discussion of the point and with her conclusion," *id.* at 503, we believe that Justice Breyer's crucial fifth vote endorsed the proposition that a state requirement could stem from a state common law tort action premised on the breach of a standard of care. *See also Horn v. Thoratec Corp.*, 376 F.3d 163, 175-76 (discussing this tension in detail and reaching the same conclusion); *but see id.* at 182-84 and n. 30 (Fuentes, *J.*, dissenting).

Since *Lohr*, the majority of circuits have applied the above-described framework to conclude that common law tort actions as to PMA-approved devices, in contrast to § 510-cleared devices, are preempted by the MDA. *See Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997).[15] These circuits have all concluded that (1) approval through the PMA process, unlike the § 510(k) process, amounts to a federal device-specific requirement, and (2) common law tort actions that allege liability as to a PMA-approved device, notwithstanding that device's compliance with the PMA-approved standards, would conflict with that federal device-specific requirement. *See Horn*, 376 F.3d at 170-179; *Martin*, 254 F.3d at 579-584; *Brooks*, 273 F.3d at 795-799; *Kemp*, 231 F.3d at 225-232; *Mitchell*, 126 F.3d at 911-914. Only the Eleventh Circuit has reached the opposite conclusion, holding that approval through the PMA process does not constitute a federal device-specific requirement. *See Goodlin v. Medtronic*, Inc., 167 F.3d 1367, 1376-77 (11th Cir. 1999).[16]

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[15]The Seventh Circuit recently reaffirmed that conclusion in *McMullen v. Medtronic*, 421 F.3d 482 (7th Cir. 2005).

[16]The Tenth Circuit has also indicated, in a non-PMA context, its agreement with the principle that state common law actions premised on the breach of a general duty of care cannot be preempted by the MDA. *See Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997).

Meanwhile, in the years since *Lohr* was decided, various state courts have divided over this issue. *Compare, e.g., Worthy v. Collagen Corp.*, 967 S.W.2d 360, 376-77 (Tex. 1998) (holding that common-law claims that alleged liability notwithstanding device's adherence to PMA-approved standards were preempted); *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 887-88 (Cal. Ct. App. 1997) (same); *Green v. Dolsky*, 685

C.

We now turn to the instant appeal of the district court's March 14, 2002 order dismissing many of the Riegels' claims on preemption grounds. We note, initially, that our *Becker* decision clearly indicated that tort law claims as to a PMA-approved device would be preempted by Section 360k(a) of the MDA. *See Becker*, 66 F.3d at 20. Because the Supreme Court subsequently spoke to the issue of Section 360k(a)'s preemptive scope in *Lohr*, however, we must revisit the issue to determine whether *Becker* is still good law. *See, e.g., Taylor v. Vt. Dep't of Educ.*, 313 F.3d 768, 782-83 (2d Cir. 2002).

Thus, following the *Lohr* Court, our analysis proceeds in two parts. First, we must consider whether, when a device such as the Evergreen Balloon Catheter obtains approval pursuant to the PMA process, it is subject to a "requirement applicable under this Act," *i.e.*, a federal device-specific requirement. Second, we must analyze the Riegels' tort claims to determine whether there is a conflict between that device-specific requirement and "any of the liability-creating premises of the [Riegels'] state-law tort suit." *Lohr*, 518 U.S. at 508 (Breyer, *J.*, concurring in part and concurring in the judgment).

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A.2d 110, 117-18 (Pa. 1996) (same) *with Weiland v. Tele[c]tronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1152-53 (Ill. 1999) (holding that such claims as to PMA-approved devices were not preempted); *Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16, 20-21 (N.Y. App. Div. 1997) (same); *Wutzke v. Schwaegler, et. al.*, 940 P.2d 1386, 1390-92 (Wash. Ct. App. 1997) (same); *Mears v. Marshall*, 944 P.2d 984, 992-996 (Or. Ct. App.) (same); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771-773 (Cal. Ct. App. 1996) (same).

We agree with the majority of circuits that have held that the relatively small subset of PMA-approved devices – in contrast to the much larger population of § 510(k)-cleared devices – are subject to federal device-specific requirements. In holding that § 510(k) clearance did not give rise to a federal device-specific requirement, the *Lohr* Court explicitly distinguished between the § 510(k) process and the PMA process, stating that the two processes were "by no means comparable." *Lohr*, 518 U.S. at 478-79. Indeed, the *Lohr* Court expressly emphasized that (1) the § 510(k) process was focused on equivalence rather than safety; (2) the FDA itself stated that § 510(k) clearance did not "denote official FDA approval"; (3) the § 510(k) exemption did not appear to have been "intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents"; and (4) § 510(k) clearance could not be viewed as "requir[ing] [the device] to take any particular form for any particular reason." *Lohr*, 518 U.S. at 493-94.

The PMA process utterly diverges from the § 510(k) process in each of these respects. First, although clearance through the § 510(k) process simply means that a device is substantially equivalent to a pre-existing device – which may or may not be safe and effective – approval through the PMA process requires reasonable assurance of the device's substantive safety and effectiveness. Second, whereas § 510(k) clearance does not indicate official FDA approval, the FDA has made clear that approval through the PMA process *does* denote such official approval. Indeed, the FDA explains on its website that "PMA is the most stringent type of device marketing application required by FDA. . . . PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s)." *See* http://www.fda.gov/cdrh/

devadvice/pma/ (last visited April 28, 2006). Third, although the § 510(k) process essentially froze the status quo with respect to pre-1976 devices and their substantial equivalents, the PMA process was created as an entirely new regime for devices that were not substantially equivalent to older devices. Finally, whereas § 510(k) clearance does not reflect the FDA's determination that the device should "take any particular form for any particular reason," *Lohr*, 518 U.S. at 493, the PMA process expressly provides the FDA with the power to require the device to take a particular form in order to be approved as safe and effective. As noted above, once the FDA has concluded its review, it can issue an "approvable letter" stating that the FDA believes it can approve the application if "specific conditions" are agreed to by the applicant. *See* 21 C.F.R. § 814.44(e). Alternatively, if the FDA "believes that the application may not be approved," it can "send the applicant a not approvable letter. . . .[that] will describe the deficiencies in the application...and, where practical, will identify measures required to place the PMA in approvable form." 21 C.F.R. § 814.44(f).

Moreover, once a device has obtained PMA approval, the manufacturer cannot make any changes that might affect the safety and effectiveness of the device without further FDA approval. At that point, therefore, the device is clearly subject to the federal, device-specific requirement of adhering to the standards contained in its individual, federally approved PMA. The Riegels have argued that manufacturers of § 510(k)-cleared devices are also precluded from making changes without FDA approval, and that this did not prevent the *Lohr* Court from finding that § 510(k) clearance imposed no device-specific requirements. But their premise is not entirely accurate. As noted above, manufacturers of § 510(k)-cleared devices have broader latitude to make changes without FDA approval than

do manufacturers of PMAapproved devices, given that they must only obtain approval when making significant changes, *see* 21 C.F.R. § 807.81(a)(3), as opposed to any change that "affect[s] the safety or effectiveness of the device," *see* 21 C.F.R. § 814.39(a). This distinction makes sense: the only issue governing § 510(k) clearance is whether the device is substantially equivalent to a pre-existing device that did not go through the PMA process. Thus, unless a significant change is made to a § 510(k)-cleared device, it will presumably still be substantially equivalent to the pre-existing device, and there is no need for further FDA review. By contrast, PMA approval explicitly signifies the FDA's substantive approval of the device's reasonable safety and effectiveness, as the device is currently constituted, and it therefore naturally follows that any changes to a PMA-approved device that might affect the device's safety and effectiveness will require further FDA approval.

For these reasons, we conclude that the Evergreen Balloon Catheter, a PMA-approved device, was subject to the federal device-specific requirement of complying with the particular standards set forth in its approved PMA application. It is true that, as the dissent states, *see post* at **[52a]**, here the FDA approved Medtronic's PMA application for the Evergreen Balloon Catheter without invoking its power to require additional alterations. As such, the only documents in the record from the FDA to Medtronic are generic letters informing Medtronic that the Evergreen Ballon Catheter has obtained PMA approval and that Medtronic must comply with the generally applicable "Conditions of Approval" governing all PMA devices. We believe, however, that this is not relevant to the analysis. Had the FDA believed that the Evergreen Balloon Catheter, as constituted at the time Medtronic submitted its PMA application for the device, was not reasonably safe and effective, it certainly would have had the power to condition

PMA approval on implementation of the changes that the FDA believed were necessary. Alternatively, as the dissent points out, the FDA could also have deemed it appropriate to promulgate performance standards applicable to catheters such as the Evergreen Balloon Catheter, pursuant to 21 C.F.R. § 861.1(b)(3). *Post* at **[52a]**. Apparently, however, the FDA concluded that the Evergreen Balloon Catheter was safe and effective as currently constituted. It would be illogical to hold that because the FDA, after rigorous review, deemed the PMA application for the Evergreen Balloon Catheter acceptable in its present form, the Evergreen Balloon Catheter is less subject to a device-specific regulation than are devices whose initial PMA applications are inadequate and which obtain PMA approval only after significant back-and-forth with the FDA. Once the PMA process is complete, all PMA-approved devices are subject to the same federal device-specific regulation: complying with the standards set forth in their individual approved PMA applications.

The Riegels have also argued that with regard to their failure-to-warn claim relating to the labeling of the Evergreen Balloon Catheter, there is no applicable federal device-specific requirement because (1) the only federal regulation governing the substance of the Evergreen Balloon Catheter's label was 21 C.F.R. § 801.109, the same general regulation that the *Lohr* Court found not to be sufficiently device-specific to warrant preemption of the labeling claims as to the § 510(k)-cleared pacemaker device at issue, *see Lohr*, 518 U.S. at 497-501; and (2) under 21 C.F.R. §§ 814.39(d)(1)-(2), manufacturers of PMA-approved devices can make certain labeling changes without pre-approval from the FDA, such as labeling changes that add or strengthen a contraindication, add or strengthen an instruction, or delete misleading, false, or unsupported information. The flaw in this argument is that, unlike in *Lohr*, here the FDA explicitly approved the labeling of the Evergreen

Balloon Catheter through the PMA process. Indeed, when Medtronic wanted to revise the Evergreen Balloon Catheter's label, it submitted PMA supplements that requested approval for those revisions, and the FDA granted that approval. Thus, we need not reach the question of whether, had Medtronic subsequently changed the catheter's label pursuant to the §§ 814.39(d) process that permits certain changes without FDA approval, failure-to-warn claims as to that label would be preempted, because here there is no evidence that Medtronic ever made changes to the catheter's label other than through the PMA process.

Finally, we note the dissent's concern about the FDA's ability to "do an adequate job of ensuring the safety of medical devices," and its discussion of specific instances in which the FDA approved, via the PMA process, medical devices that were later proven unsafe. *Post* at **[48a-50a]**. We agree that it is imperative for the FDA to protect consumers' safety by exercising careful and reasoned judgment both in (1) evaluating whether to grant PMA approval in the first place (and determining which, if any, changes must be made in the device for it to obtain such approval) and (2) reviewing the postapproval annual reports, adverse reaction reports, and device defect reports that must be submitted by manufacturers of PMA-approved devices in order to determine whether the continuation of such approval is appropriate. As a court, we are constrained to observe, however, that the FDA's level of success in carrying out these responsibilities, rather than bearing on the legal question of whether PMA approval reflects a federal device-specific requirement, is ultimately a policy matter for Congress and the Executive to address.

2.

Having ruled that the Evergreen Balloon Catheter was subject to the federal device specific requirement of complying with the standards in its approved PMA application, we now move to the question of whether the Riegels' claims would, if successful, result in state "requirements" that differed from or added to those standards. We conclude that they would.

The Supreme Court first addressed the issue of whether a preemption provision's reference to state "requirements" encompasses state common law tort suits, in addition to state statute or other positive enactments, in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). There, in the context of interpreting the preemption provision contained in the Public Health Cigarette Smoking Act of 1969, 15 U.S.C. § 1334(b), a majority of the Court answered that question in the affirmative. *See id.* at 521-22 ("The phrase 'no requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules. . . . [C]ommon-law damages actions of the sort raised by petitioner are premised on the existence of a legal duty, and it is difficult to say that such actions do not impose 'requirements or prohibitions.[']") (plurality opinion); *see also id.* at 548 (Scalia, *J.*, concurring in the judgment in part and dissenting in part).

In *Lohr*, the five justices who endorsed the view that § 360k(a)'s reference to state "requirements" encompassed state common law tort lawsuits explicitly invoked *Cipollone* in reaching that conclusion. *See Lohr*, 518 U.S. at 504-05 (Breyer, *J.*, concurring in part and concurring in the judgment) ("[I]n *Cipollone*. . ., the Court made clear that similar language 'easily' encompassed tort actions because '[state] regulation can be as effectively exerted through an award of damages as

through some form of preventative relief.' This rationale would seem applicable to the quite similar circumstances here.") (internal citations omitted; alteration in original); *id.* at 510-511 (O'Connor, *J.*, concurring in part and dissenting in part) ("We recently addressed a similar question in *Cipollone*. . . .A majority of the Court agreed that state common-law damages actions do impose 'requirements.'. . .That rationale is equally applicable in the present context.").

Since *Lohr*, the Supreme Court has held firm to the view that state "requirements" can be created by state common law actions. Just last year in *Bates v. Dow Agrosciences LLC*, the Court held – in the context of interpreting the Federal Insecticide, Fungicide, and Rodenticide Act's provision that "State[s] shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this Act," 7 U.S.C. § 136v(b) – that the Fifth Circuit had "correctly [held] that the term 'requirements' in § 136v(b) reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties." 125 S. Ct. 1788, 1798 (2005). Thus, the *Bates* Court explained that the plaintiffs' fraud and negligent-failure-to-warn claims, which were premised on a deficiency in the labeling or packaging of the product at issue, would be preempted by FIFRA, unless the duties that the claims implicated were simply equivalent to FIFRA's own misbranding provisions, rather than adding to or differing from the FIFRA provisions. *Id.* at 1800.[17]

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[17]By contrast, the Court held that the plaintiffs' claims for defective design, defective manufacture, and negligent testing were not preempted, because those claims did not relate to the labeling and packaging of the product, and FIFRA's preemption provision only preempted "requirements for labeling or packaging." *Id.* at 1799. The Court acknowledged that the plaintiffs' success on those claims might prompt the manufacturer to alter

We thus conclude that the Riegels' claims for strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, and sale would, if successful, impose state requirements that differed from, or added to, the PMA-approved standards for the Evergreen Balloon Catheter. These claims do not rest on the premise that the particular catheter used during Mr. Riegel's angioplasty deviated from the standards contained in the approved PMA application for the Evergreen Balloon Catheter. Rather, the liability-creating premise of all of these claims is that the Evergreen Balloon Catheter itself, in its present PMA-approved form, is in some way defective and therefore requires modification.

The Riegels assert that a verdict in their favor would simply stem from generally applicable state common law duties, such as the duty to use due care and the duty to inform users and purchasers of about [sic] relevant risks. Therefore, they argue, such a verdict could not possibly create a state "requirement" that adds to, or differs from, any federal device-specific requirements for the Evergreen Balloon Catheter. We disagree. The Supreme Court made clear in *Cipollone*, *Lohr*, and *Bates* that common law actions, which are premised on the alleged violation of a legal duty, do impose requirements. As Justice O'Connor put it in *Lohr*, "state common-law damages actions

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its product in ways that, in turn, would induce the manufacturer to voluntarily make corresponding changes in its label. *Id.* at 1798-99. The Court explained, however, that this did not mean that such claims could be viewed as setting forth labeling and manufacturing requirements: "[a]n occurrence that merely motivates an optional decision does not qualify as a requirement." *Id.* at 1798. The Court also held that the plaintiffs' breach of express warranty claim was not preempted, because that claim asked only that "a manufacturer make good on the contractual commitment that it voluntarily undertook by placing that warranty on its product." *Id.* at 1799.

operate to require manufacturers to comply with common-law duties." *Lohr*, 518 U.S. at 510 (O'Connor, *J.*, concurring in part and dissenting in part). Indeed, a verdict in the Riegels' favor on any of these claims would represent a finding that the Evergreen Balloon Catheter had not adhered to the various state common law duties implicated by those claims, *e.g.*, that its design did not comport with the duty of due care, or that its labeling did not comport with the duty to warn. Such a verdict would clearly differ from the FDA's PMA approval of the device (and its related packaging, labeling, distribution, and so on) as being reasonably safe and effective, and, moreover, from the FDA's prohibition against making any modifications affecting the device's safety and effectiveness without first obtaining FDA approval.

Indeed, such a situation would be quite analogous to the hypothetical situation posed by Justice Breyer in his *Lohr* concurrence, in which, notwithstanding a federal requirement for a 2-inch hearing wire in a particular hearing aid, a plaintiff brought a tort claim relating to the same hearing aid that premised liability on the manufacturer's failure to use a wire that was 1-inch or less. *Lohr*, 518 U.S. at 504 (Breyer, *J.*, concurring in part and concurring in the judgment). Justice Breyer clearly thought that such a claim would be preempted. *Id.* Here, similarly, there is a federal requirement that the Evergreen Balloon Catheter adhere to the standards set forth in its approved PMA application, absent further FDA approval. Yet the Riegels' claims would premise liability on Medtronic's failure to have done something with the Evergreen Balloon Cath[et]er other than adhere to the PMA-approved standards.

In fact, it is unclear what a manufacturer of a PMA-approved medical device would do when faced with such a jury verdict on a plaintiff's common law claims, given that the manufacturer would nonetheless be unable to make any

modifications affecting the device's safety and effectiveness without obtaining further FDA approval. Moreover, it is certainly conceivable that different juries would reach conflicting verdicts about the same medical devices, thus rendering it almost impossible for a device to comply simultaneously with its federal PMA (which, after all, can only change after an extensive process) and with the various verdicts issued by different juries around the country. In this regard, a finding of preemption is consistent with another purpose evident in the MDA's legislative history: its desire to ensure that "innovations in medical device technology are not stifled by unnecessary restrictions," and its corresponding recognition that "if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened." H.R. Rep. No. 94-853, at 12, 45.

As such, although we agree with the dissent's recognition of a general presumption against preemption, and with the dissent's comment that the legislative history of the MDA is silent as to the specific issue of preemption of state tort liability, *see post* at **[43a-47a]**, we believe that the above discussed Supreme Court precedent makes clear that Section 360k(a)'s reference to state "requirements" should be interpreted to encompass state common law actions. We note, too, that the dissent's argument regarding legislative history and intent is far more persuasive with respect to § 510(k)-cleared devices than with PMA-approved devices. As the Supreme Court stated in *Lohr*, the § 510(k) process appears to have been designed to "maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents. That status quo included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design." *Lohr*, 518 U.S. at 494. By contrast, the PMA regime represented an entirely

new approach of ensuring consumer safety through increased federal regulation and oversight. It is thus much less clear that the continuation of the previous tort remedies in the PMA context is consistent with the MDA's purpose. *See* Benjamin A. Goldberger, *The Evolution of Substantial Equivalence in FDA's Premarket Review of Medical Devices*, 56 FOOD DRUG. L.J. 317, 332-33 (2001) ("Finding preemption for devices that received PMAs while holding that 510(k)'d devices cannot benefit from preemption is consistent entirely with the original purpose of substantial equivalence doctrine. Developed as a method to ensure economic parity between post-enactment and pre-enactment devices, a substantial equivalence finding allows a company to market devices as others did before the MDA, complete with exposure to tort liability. A PMA, on the other hand, brings a device completely within the scope of the federal regulation as Congress had envisioned it, and, thus is preemptive.").

For these reasons, we adhere to the rationale initially set forth by this Court in *Becker*, and hold that the Riegels' strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, and sale claims are preempted by Section 360k(a) of the MDA. We thus affirm the district court's March 14, 2002 order granting summary judgment to Medtronic on these claims on preemption grounds.

By the same token, we agree with the district court's conclusion that the Riegels' negligent manufacturing claim was not preempted, to the extent that it rested on the allegation that the particular Evergreen Balloon Catheter that was deployed during Mr. Riegel's angioplasty had not been manufactured in accordance with the PMA-approved standards. A jury verdict in the Riegels' favor on this claim would not have imposed state requirements that differed from, or added to, the

PMA-approved standards for this device, but would instead have simply sought recovery for Medtronic's alleged deviation from those standards. *See Lohr*, 518 U.S. at 513 (O'Connor, *J.*, concurring in part and dissenting in part) ("Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is 'different from, or in addition to,' requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.") (emphasis in original).

We conclude this portion of our analysis by emphasizing that – contrary to the dissent's fear that "the decision today will deprive those who were injured by an unreasonably dangerous medical device of any remedy whatsoever," *post* at **[46a]** – the scope of our decision is actually quite limited. As noted above, the vast majority of Class III medical devices enter the market pursuant to the § 510(k) process, not the PMA process. The Supreme Court has already held in *Lohr* that tort claims as to § 510(k)-cleared devices are not preempted. Moreover, our decision today does not even hold that all state tort claims as to PMA-approved devices are preempted. On the contrary, as set forth above, tort claims that are premised on a manufacturer's deviation from the standards set forth in the device's approved PMA application – such as the Riegels' negligent manufacturing claim – are in no way preempted. Only those claims that allege liability despite a PMA-approved device's adherence to those standards are, pursuant to this decision, preempted. As one article recently noted, "[t]his is a relatively small universe of cases." *See* Gregory J. Scandaglia and Therese L. Tully, 59 FOOD DRUG L.J. 245, 263-64 (2004).

We also question the dissent's conclusion that our holding will necessarily remove the incentives for manufacturers of PMA-approved devices to continue improving the safety of their products once they obtain approval and to alert the FDA of the need for changes as new data becomes available. *See post* at **[48a, 53a]**. As a condition of continued approval, manufacturers of PMA-approved products are already required to provide the FDA with annual reports that summarize any "unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices," 21 C.F.R. § 814(b)(2)(i); and any "reports in the scientific literature concerning the device," 21 C.F.R. § 814(b)(2)(ii). Such manufacturers are also specifically required, as a condition of continued approval, to notify the FDA within ten days of any adverse reactions or device defects. *See supra* page [11a]. Additionally, such manufacturers are also likely to be in competition with other manufacturers of similar devices, providing another incentive for them to continue improving their own devices. In any event, we ultimately view this as a policy issue for the legislative and executive branches rather than a legal question. Should Congress conclude that the preemption of the state tort actions at issue in this case creates undesirable incentives for manufacturers of PMA-approved devices, it is entirely free to amend Section 360k(a) to make clear that its reference to state "requirements" does not include state tort actions.

Finally, we note that our conclusion is further supported by the FDA's recent determination that preemption is warranted with respect to this universe of cases, as indicated by the content of the May 14, 2004 amicus curiae brief that the FDA submitted upon request to the Third Circuit in connection with the *Horn* case, which implicated the same issue that we address here. *See* 2004 WL 1143720 (amicus brief); *Horn*, 176 F.3d at 177-79 ("The FDA has clearly expressed its view that PMA

approval in this particular case requires preemption. The FDA conceives of [the plaintiff's] state common law claims as imposing a 'requirement' which is 'different' from that imposed by the FDA in the PMA process, and thus requiring preemption. . . A majority of the Court in *Lohr* emphasized that the FDA is 'uniquely qualified to determine whether a particular form of state law. . .should be pre-empted.'") (quoting *Lohr*, 518 U.S. at 496). It is certainly true that the FDA previously took a different view, but as the Third Circuit noted in *Horn*, "an agency may change its course so long as it can justify its change with a 'reasoned analysis,'" a standard satisfied here. *Id.* (citing *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983)).

IV.

We now turn to the December 2, 2003 order that granted summary judgment to Medtronic on the Riegels' non-preempted negligent manufacturing claim.

The legal framework governing this claim is undisputed. Because the Riegels do not have the actual Evergreen Balloon Catheter that was used during Mr. Riegel's angioplasty, they can prevail only by proving by circumstantial evidence that it must have been defective. As the New York Court of Appeals recently explained, "[i]n order to proceed in the absence of evidence identifying a specific flaw, a plaintiff must prove that the product did not perform as intended and exclude all other causes for the product's failure that are not attributable to defendants." *Speller v. Sears, Roebuck and Co.*, 100 N.Y.2d 38, 41 (N.Y. 2003).

Medtronic, with reference to expert opinions, has argued that the Evergreen Balloon Catheter used during Mr. Riegel's

angioplasty burst not because it was negligently manufactured, but rather because (1) it was inflated to 10 atmospheres, even though the label stated that it should not be inflated more than 8 atmospheres; (2) it was inserted into an artery that was "diffusely diseased" and "heavily calcified," even though the label stated that it should not be used in such instances (because calcium spicules can puncture the catheter); and/or (3) Dr. Roccario used metal stents that could have punctured the catheter.

Thus, to overcome Medtronic's arguments and survive summary judgment, the Riegels had to come forward with competent evidence excluding Medtronic's proferred alternative causes as the actual origin of the catheter's rupture. *See Speller*, 100 N.Y.2d at 42 (holding that where the defendants argued that the fire in question had been caused not by their refrigerator's wiring, but rather by the plaintiff's stove, "[i]n order to withstand summary judgment, plaintiffs were required to come forward with competent evidence excluding the stove as the origin of the fire").

We agree with the district court that the Riegels did not come forward with competent evidence excluding Medtronic's proffered causes as the origin of the rupture. It is undisputed that Dr. Roccario, in performing Mr. Riegel's angioplasty, inflated the balloon catheter to ten atmospheres, which is two atmospheres and approximately 29.4 pounds per square inch beyond the maximum rated burst pressure explicitly specified on the device label. The Riegels have argued, through Dr. Roccario's affidavit, that "exceeding the maximum recommended atmospheres of eight (8) to ten (10) atmospheres was not outside the window of [the device's] testing in laboratory settings. . . and inflations to ten (10) atmospheres was based upon my past experience with the product and was

called for in the circumstances herein presented in order to attempt to obtain the angiographic appearance that I desired rather than what I was presented with at the time and instead of reintroducing still another balloon." Although it may well be that inflating the balloon catheter up to ten atmospheres was the best decision under the circumstances, this does not indicate that the inflation was not the cause of the catheter's rupture.

It is similarly undisputed that Mr. Riegel had heavily calcified arteries, and that the label for the Evergreen Balloon Catheter contraindicated its use in such an instance. Dr. Roccario has stated that "it is all but routine today at this point in the development of the medical science in question for a PTCA [percutaneous transluminal coronary angioplasty] to go forward under such circumstances." Again, however, this does not mean that in this particular instance, we can exclude the calcified nature of Mr. Riegel's artery as a cause for the catheter's rupture. Indeed, Dr. Roccario himself – while stating that "there was simply nothing about the procedures that I undertook or the medical decisions and choices that I made on May 10, 1996 which in my professional medical opinion in any way contributed to the bursting of this particular Evergreen 3.0-20mm balloon" – has not actually opined that the catheter must have burst as a result of a manufacturing defect.

The only affirmative evidence that the Riegels have adduced in support of their claim that the catheter must have had a manufacturing defect is the report of their expert, engineer Ted Milo, who offered the view that based on the nature of Mr. Riegel's injury, the catheter must have burst not longitudinally, but radially, which – in his view – apparently signified a manufacturing defect. The district court found, however, that Milo's conclusion that the catheter had burst radially was based on "sheer surmise and conjecture rather than

on any scientific basis," and therefore found it to be insufficiently substantiated to be admissible as expert testimony. We agree, and thus conclude that the district court did not abuse its discretion in refusing to admit this evidence. *See Raskin v. The Wyatt Co.*, 125 F.3d 55, 65-66 (2d Cir. 1997) (explaining that district court has broad discretion in deciding whether to admit evidence, that we therefore review evidentiary rulings for manifest error, and that this "same standard of review applies to a district court's evidentiary rulings on expert testimony").

The district court identified serious flaws in Milo's expert opinion. First, Milo did not explain the basis of his conclusion that Mr. Riegel's injury was more indicative of a radial failure than a longitudinal failure. Second, even assuming *arguendo* that the balloon burst radially rather than longitudinally, Milo did not explain why a radial failure could not itself result from the causes that Medtronic proffers here: namely, overinflation of the catheter or by punctures caused by calcifications. Indeed, the district court also pointed out that Milo's own exhibit indicated that even some non-longitudinal failures are caused not by manufacturing defects, but rather by overpressurization or punctures from calcified lesions.[18] The Riegels have not responded to this point on appeal. We also note that in his deposition, when Milo was asked for his response to another expert opinion that "the probable cause of rupture of the balloon catheter was not a manufacturing defect, but rather puncture of the balloon by either a spicule of calcium

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[18]We note that Milo seems to have simply assumed that because Dr. Roccario used a rotoblator to remove the calcium deposits from Mr. Riegel's artery before inserting the Evergreen Balloon Catheter, the device's contraindication for patients with calcified arteries "would no longer be relevant." He did not even address the possibility that some calcium spicules could have remained.

in the vessel wall or a portion of the previously implanted metal stents," he responded, "I have no opinion."

Although the Riegels argue that Milo's theories should have been evaluated by a jury rather than the district judge, this Circuit has explained that it is appropriate for the district court to determine the admissibility of scientific evidence and to rely only on admissible evidence in ruling on summary judgment. *See, e.g., Amorgianos v. National Railroad Passenger Corp.*, 303 F.3d 256, 271 (2d Cir. 2002) (affirming grant of summary judgment after district court had ruled the plaintiff's expert report inadmissible); *Raskin*, 125 F.3d at 66 (stating that "an expert's report is not a talisman against summary judgment"). We believe that the district court was well within its discretion in concluding that Milo's opinion was not an admissible expert opinion and therefore could not serve as a basis for demonstrating a manufacturing defect. An expert opinion requires some explanation as to how the expert came to his conclusion and what methodologies or evidence substantiate that conclusion. *See* Fed. R. Evid. 702 ("If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case"). In this case, Milo essentially provided no explanation as to how he had reached his conclusion that the rupture must have been caused by a manufacturing defect, and himself seems to have backed away from this conclusion in his deposition. It was therefore appropriate for the district court to exclude his opinion.

As a result, because there was no competent evidence excluding Medtronic's proffered causes – particularly, encounter with a calcium spicule in the artery and/or the over-inflation of the catheter – as the origin of the rupture of the Evergreen Balloon Catheter, there were no genuine issues of material fact for a jury on this claim. Therefore, we agree with the district court that the Riegels "failed to submit sufficient evidence from which a fair-minded trier of fact [could] reasonably conclude that Plaintiff excluded all other causes of the burst," and affirm the court's December 2, 2003 dismissal of their negligent manufacturing claim.

V.

For the foregoing reasons, we hereby affirm the district court's March 14, 2002 and December 2, 2003 orders that, collectively, granted summary judgment to Medtronic on all of the Riegels' claims.

POOLER, Circuit Judge, concurring in part and dissenting in part.

The majority today holds that when a device has gone through the PMA process, all state tort claims regarding the design or labeling of that device are preempted. While the majority opinion skillfully negotiates a complex and splintered area of the law, I believe it overlooks two critical aspects of the preemption analysis: the presumption against preemption and congressional intent. Because both these factors weigh against a finding of preemption, I would resolve the close question of whether the PMA process constitutes a device-specific federal requirement in the negative and find that the Riegel's tort claims are not preempted. Therefore, I respectfully dissent.

I.

The Supreme Court has instructed that "[a]lthough our analysis of the scope of the preemption statute must begin with its text, . . . that interpretation is informed by two presumptions about the nature of pre-emption." Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (citing Gade v. Nat'l Solid Wastes Mgmt. Ass'n., 505 U.S. 88, 111 (1992) (Kennedy, J., concurring)). First, we begin with "the presumption that state or local regulation of matters related to health or safety is not invalidated" by preemption. Hillsborough Couty v. Automated Med. Labs., Inc., 471 U.S. 707, 715 (1985). Second, "'[t]he purpose of Congress is the ultimate touchstone' of preemption analysis." Cipllone [sic] v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (quoting Malone v. White Motor Corp., 435 U.S. 497, 504 (1978)).

Out of respect for the fact that "the States are independent sovereigns in our federal system," we assume that "the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Lohr, 518 U.S. at 485. Thus, where the states have a long tradition of providing a tort remedy to protect their citizens, the presumption against preemption is particularly strong. See Bates v. Dow Agrosciences LLC, 544 U.S. 431, —, 125 S.Ct. 1788, 1801 (2005) ("The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption."). "States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." Lohr, 518 U.S. at 475. In particular, states have generally provided tort remedies to their citizens when they are injured by defective products.

As the majority notes, Congress enacted the MDA "to provide for the safety and effectiveness of medical devices intended for human use." 90 Stat. 539. One major impetus for the legislation was problems with the Dalkon Shield, an intrauterine contraceptive device that resulted in a high percentage of inadvertent pregnancies, serious infections, and even some deaths. Lohr, 518 U.S. at 476; see also H.R. Rep. No. 94-853, at 8 (1976). Concern about better protecting the public from unsafe devices runs throughout the legislative history of the MDA. See, e.g., H.R. Rep. No. 94-853, at 10 ("[P]resent and potential hazards, and the need for reliability and effectiveness of devices necessitates explicit legislation." (quoting the Report of the Cooper Committee, convened in 1969 to study medical devices)). Senator Edward Kennedy, a major proponent of the MDA, noted that "[t]he legislation is written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions." 94 Cong. Rec. 10688. Thus, although legislators may have had a secondary concern about stifling innovation through over regulation, see H.R. Rep. No. 94-853, at 12, their primary purpose was clearly to protect consumers from unsafe medical devices.

The legislative history of the MDA provides no indication that Congress considered the preemption of state tort liability or even that Congress had any concern about litigation hampering the development of useful medical devices. See Lohr, 518 U.S. at 490–91 (plurality opinion). Similarly, contemporaneous analyses of the MDA are silent on the possibility of preemption of state tort claims. Id. at 491 n.13. If Congress actually intended to preempt all state tort claims for defective devices, it seems unlikely that such a dramatic change from existing law would go entirely unmentioned, particularly considering the well-known, ongoing litigation over such devices as the Dalkon Shield. Id. at 491. The only discussion

of the preemption provision that I have found indicates that it was primarily focused on preventing state regulatory schemes, which some states had adopted in the absence of federal regulation on the topic. H.R. Rep. No. 94-853, at 45–46. State tort remedies are not mentioned. Id.

"This silence takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct." Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984). It is hard to believe that Congress, while enacting the FDA to protect consumers, intended to preempt all state tort claims, when that result will have such negative consequences for those same consumers. Because the MDA does not provide a federal remedy for injured consumers, the decision today will deprive those who were injured by an unreasonably dangerous medical device of any remedy whatsoever. If the FDA or the manufacturer negligently fails to consider a potential danger posed by a medical device, it is the injured consumer alone who will pay the price. Worse still, because the Supreme Court has found that fraud on the FDA claims are impliedly preempted, see Buckman v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001), even if PMA was obtained through intentional misrepresentation on the part of the manufacturer, by, for example, failing to report studies indicating substantial risks, the injured consumer cannot recover any compensation for her injury. "If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." Bates, 125 S.Ct. at 1801 (citing Silkwood, 464 U.S. at 251).

Furthermore, the idea that all state tort claims are unambiguously preempted is "particularly dubious" considering it appears that until relatively recently neither the industry nor the FDA thought such claims were preempted. See Bates, 125

S.Ct. at 1801. It was over fifteen years after the MDA was enacted before the industry began to assert preemption based on FDA approval as a defense to state tort suits. See Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1381 (11th Cir. 1999) (noting that Slater v. Optical Radiation Corp., 756 F.Supp. 370 (N.D. Ill. 1991), aff'd, 961 F.2d 1330 (7th Cir. 1992), was one of the earliest cases in which this argument was raised). As recently as 1997, the FDA took the position that common law duties would be preempted only when the FDA has expressly imposed through regulation or order a specific substantive requirement applicable to a particular medical device and the state common law would impose a different or additional requirement on the same device.[19] See Proposed Rule: Medical Devices; Preemption of State Product Liability Claims, 62 Fed. Reg. 65384, 65387 (Dec. 12, 1997); Brief for United States as Amicus Curiae Opposing Writ of Certiorari at 19, Smiths Indus. Med. Sys., Inc. v. Kernats, 520 U.S. 1208 (1997) (No. 96-1405), 1997 WL 33561767.

Traditionally, state tort claims for negligent design or labeling have provided compensation to consumers when the manufacturer knew or should have known that the design of its product posed an unreasonable risk of harm, and the manufacturer fails to improve the design or warn the consumer about the risk. In addition, strict product liability has generally placed the burden of compensating injured users on manufacturers because they are in a better position to insure against the risk and spread that cost among those who benefit from the product. See Ashley W. Warren, Preemption of Claims Related to Class III Medical Devices: Are the Federal

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[19]The majority argues that the agency is free to change its position provided it gives a reasoned analysis. **[Maj. op at 36]** While I assume this is true, it does not undermine the probative value of the agency's prior understanding in discerning congressional intent.

Objectives of Public Health and Safety Furthered or Hindered?, 49 SMU L. Rev. 619, 643 (1996). The finding of preemption here will place that risk entirely on those unfortunate enough to be injured by defective devices. And if manufacturers are not forced to internalize the costs of risks associated with their devices, they will have little incentive to continue to improve the safety of their products once PMA is granted. See Roger W. Bivens, Substantially Equivalent? Federal Preemption of State Common-Law Claims Involving Medical Devices, 74 Tex. L.Rev. 1087, 1120 (1996). This will undoubtedly reduce the resources expended on safety related innovations that would benefit consumers.

These problems might not in reality undermine Congress's intent to protect consumers if the FDA could generally be trusted to do an adequate job of ensuring the safety of medical devices, but there are serious reasons to doubt that this is the case. Even if the influence of the regulated industry over the agency does not undermine the FDA's effectiveness, the FDA may not have adequate resources to genuinely ensure that devices are safe or to properly and efficiently reevaluate approvals as new information becomes available.[20] See Catherine T. Struve, The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation, 5 Yale J. Health Pl'y L. & Ethics 587, 601–07 (2005).

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[20]While it is true, as the majority points out, that if the manufacturer becomes aware of new information regarding the safety of the device, then it is required to report that information to the FDA. **[Maj Op. 35–36]** This does not change the fact that, if all design claims are preempted, the manufacturer need not seek out safety-related innovations and, even in light of data indicating dangers, is free to remain entirely passive about improving safety until the FDA requires it to do so.

Despite the majority's emphasis on the large number of hours spent reviewing each PMA application, the agency's track record indicates these concerns are far from academic. A May 1993 Report from a subcommittee of the House Committee on Energy and Commerce contained several case studies in which the FDA had awarded PMA to unsafe devices, and attributed these failures to an unwillingness or inability on the part of the FDA to compel manufacturers to provide sufficient data and to critically evaluate the data provided. See Less Than the Sum of Its Parts: Reforms Needed in the Organization, Management, and Resources of the Food and Drug Administration's Center for Devices and Radiological Health, Report by the House Subcommittee on Oversight and Investigations of the Committee On Energy and Commerce, at 1–3, 21 (Comm. Print 103-N 1993). For example, the FDA granted PMA to bovine collagen in 1981, despite numerous flaws in the clinical data, including the Company's failure to submit safety information appropriately. Id. at 23. The FDA also failed to take prompt action when the company marketing the device underreported adverse reactions and made unreported, misleading labeling changes. Id. at 24. Because of disputes over procedure between the FDA and the company, it was not until 1990 that the FDA required the company to conduct an analysis of complaints associated with bovine collagen use. Id. at 24. In 1991, the FDA recognized that there was an association between the use of bovine collagen and autoimmune responses, including serious diseases. Id. at 24. The report also includes other examples of the FDA's failure to recognize and respond to risks associated with medical devices. Id. at 21–34. Thus, there is reason for concern if FDA oversight is the only incentive to improve the safety of medical devices.

The majority considers these concerns to be mere policy matters to be left to Congress and irrelevant to the legal

analysis of preemption. **[Maj. op at 28, 36]** I note these issues only to highlight how the majority's holding fails to consider Congress's intent to protect consumers. Because the Supreme Court has instructed us that Congress's intent is the ultimate touchstone of preemption analysis, Cipllone [sic], 505 U.S. at 516, I cannot consider it to be irrelevant to the legal analysis in this case.

If Congress's goal in passing the MDA was to protect consumers, as it seems clear it was, then it is unlikely that it intended to preempt all state tort claims for design or labeling defects whenever a device has gone through the PMA process. Thus, I believe we must recognize a particularly strong presumption against preemption in this case.

II.

With these principles in mind, I turn to whether the particular state tort claims in this case are expressly preempted by Section 360k(a). To make this determination, the Supreme Court has instructed that we conduct "a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." Lohr, 518 U.S. at 500. Because the lack of any device-specific federal requirement makes it impossible to make such a "careful comparison" with the state tort claims in this case, I would find the Riegels' claims have not been preempted.

I agree with the majority that Lohr requires us first to determine whether the PMA process imposes a device-specific federal requirement on the Evergreen Balloon Catheter. Both the majority and concurring opinions in Lohr relied on the FDA

regulation regarding the scope of preemption under the MDA to reach the conclusion that the federal requirement must be specific. 518 U.S. at 500 (Noting the "overarching concern that preemption occur only where a particular state requirement threatens to interfere with a specific federal interest"); id. at 507 (Breyer, J., concurring) ("[T]he regulation's word 'specific' does narrow the universe of federal requirements that the agency intends to displace at least some state law."). Those regulations state that preemption will occur only when the agency "has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." 21 C.F.R. § 808.1(d).

Despite the fact that the PMA process focuses on safety and effectiveness while the 510(k) process focuses only on substantial equivalence, whatever requirements, if any, the PMA process imposes on a device are no more *specific* than those imposed by the 510(k) process. See Goodlin, 167 F.3d at 1376; Sowell v. Bausch & Lomb, Inc., 656 N.Y.S.2d 16, 20 (App. Div. 1997). And although the PMA process involves a rigorous and intensive review of a device, neither that review nor eventual approval imposes any ascertainable requirement upon the device that could be compared to any state requirement. See Goodlin, 167 F.3d at 1374–75.

The FDA's approval constitutes no more than a finding that the manufacturer has met the FDA's minimum requirements to show a device's safety and effectiveness. Cf. 21 C.F.R. § 814.45 (listing bases for denial of PMA); see also Goodlin, 167 F.3d at 1375.[21] It does not represent a reasoned

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[21] As discussed above, this was the precise position of the FDA for more than twenty years after the passage of the MDA. See Brief for United States as Amicus Curiae at 15, Smiths Indus. ("[T]hose general [PMA]

consideration and rejection by the agency of possible alternative, safer designs. If the facts showed that the FDA had actually rejected the design improvement advocated by the Riegels' through their tort claims, this might be a different case. However, here the FDA simply issued a generic approval letter. **[JA at 112–13]** Indeed, if the FDA were to determine that a particular device should be subject to substantive requirements, then it has the power to promulgate performance standards to that effect. See 21 C.F.R. § 861.1(b)(3). Such performance standards, unlike PMA, would obviously constitute specific federal requirements with preemptive effect.

The majority argues that the device at issue "was subject to the federal device-specific requirement of complying with the particular standards set forth in its approved PMA application." **[Maj. Op. at 26]** To support this proposition, the majority places substantial reliance on the fact that, once PMA has been granted, the manufacturer cannot make any changes that affect the safety and effectiveness of the device without further FDA approval. **[Maj. Op. at 25]** Yet, because the manufacturer always retains the ability to submit a PMA supplement to request approval of changes, see 21 C.F.R. § 814.39(a), the FDA cannot realistically be said to have *required* a manufacturer not to adopt a specific change until the manufacturer requests approval and is rejected. In fact, a manufacturer can even make certain changes that would enhance safety prior to getting FDA approval. See id. §814.39(d). Thus, I simply cannot conclude that "complying with the particular standards set forth in its approved PMA application" constitutes a specific federal requirement. The FDA "did not 'require' [the Evergreen Balloon Catheter] to

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criteria establish minimum standards that do not displace state law standards of care of common law duties respecting the medical device.").

take any particular form for any particular reason." Lohr, 518 U.S. at 493.

Treating a specific design or label as a requirement when the FDA might well approve a change as an improvement in safety removes any incentive for manufacturers to promptly alert the FDA to the need for changes as new safety data becomes available. See Brooks v. Howmedica, Inc., 273 F.3d 785, 800–01 (8th Cir. 2001) (in banc) (Bye, J., dissenting) (arguing there should be no preemption of claim premised on the failure to warn about risk discovered after PMA when no labeling change was sought); see also Bates, 125 S.Ct. at 1802 ("[T]he specter of damage actions may provide manufacturers with added dynamic incentives to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement.").

For the same reasons, the majority's attempt to distinguish the limitation on changes after Section 510(k) approval, which was found not to create a requirement in Lohr, is unpersuasive. The fact that, after PMA, FDA approval is required for any change affecting the safety or effectiveness of the device, rather than only for a significant change, does not make the federal requirement any more specific nor does it mean the manufacturer is required not to make changes to improve the safety of the device.

III.

Because I would find the PMA process does not impose any federal device-specific requirement, there is no need for me to reach the question of whether state tort claims would be preempted by such a requirement. The majority finds the Riegels' claims for negligent design, strict product liability,

breach of implied warranty, and loss of consortium have been preempted because PMA requires Medtronic not to alter the design, manufacturing, or labeling of the Evergreen Balloon Catheter. Despite the purpose of the MDA to protect consumers, I agree with the majority that at least some state tort claims could be preempted because they can impose "requirements" that are different from or in addition to the federal requirements. See Bates, 125 S.Ct. at 1798 (holding in the context of a different preemption provision that "the term 'requirements' . . . reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties"). Nevertheless, because there is no specific federal requirement to compare to these state claims, and nothing prevents Medtronic from improving the design, manufacturing, or labeling of the Balloon Catheter, I would not find these claims have been preempted.

IV.

For the foregoing reasons, I respectfully dissent from the majority's finding of preemption. I do agree, however, that summary judgment was properly granted as to the Riegels' negligent manufacturing claim and concur in that portion of the judgment.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

CHARLES R. RIEGEL and DONNA S. RIEGEL,

Plaintiffs,

-against-

99-CV-0649 (LEK/RWS)

MEDTRONIC, INC.,

Defendant.

MEMORANDUM-DECISION AND ORDER

I. BACKGROUND

A. Procedural History

Before the Court is Defendant's motion for summary judgment based on federal preemption and for dismissal of Plaintiffs' claim of breach of express warranty for failure to state a claim. Plaintiffs filed a complaint against Defendant in this action on April 29, 1999. The complaint sets forth five causes of action, including negligence, strict liability, breach of express warranty, breach of implied warranty, and loss of consortium. In its amended answer, Defendant sets forth as its fifth affirmative defense the doctrine of federal preemption. Ths Court issues an order limiting initial discovery to preemption issues. Discovery on federal preemption has concluded and Defendant has based this motion for summary judgment on its preemption defense.

B. Factual History

In May 1996, Plaintiff Charles Riegel underwent heart treatment as a result of a myocardial infarction. As part of this treatment, an Evergreen Balloon Catheter (the "Catheter"), manufactured by Defendant, was used for a balloon dilation of Plaintiff's coronary artery. During the inflation of the Catheter, the Catheter exploded allegedly causing Plaintiff serious injuries.

II. DISCUSSION

A. Standard of Review

Federal Rule of Civil Procedure 56 provides that summary judgment is proper where "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed R. Civ. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 322-24 (1986). Once the moving party meets its initial burden by demonstrating a right to judgment, the nonmovant must go beyond the allegations in his pleadings and set forth specific facts showing that a genuine issue of material fact exists for trial and that a reasonable jury could return a verdict for the non-moving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986).[1] Summary judgment must be granted against a plaintiff

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[1] "When moving party has carried its burden under Rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita, 475 U.S. at 586 (footnote omitted).

who fails to demonstrate facts establishing an essential element of his case. Celotex, 477 U.S. at 322-23.

On a motion for summary judgment, all facts must be viewed and all inferences must be drawn "in the light most favorable" to the non-moving party. United States v. Diebold, Inc., 369 U.S. 654, 655 (1962) (per curiam); Bechhoefer v. United States Dep't of Justice DEA, 203 F.3d 57, 59 (2d Cir. 2000). Bald assertions or conjecture unsupported by evidence are insufficient to overcome a motion for summary judgment. Carey v. Crescenzi, 923 F.2d 18, 21 (2d Cir. 1991).

"[W]hen the defendant provides convincing evidence to explain its conduct and the plaintiff's contention consists of purely conclusory allegations fo discrimination, the Court may conclude that no material issue of fact exists and it may grant summary judgment in favor of defendant." Nweke v. Prudential Ins. Co. Of Am., 25 F. Supp.2d 203, 214 (S.D.N.Y. 1998) (citing Stern v. Trustees of Columbia Univ., 131 F.3d 305, 312-14 (2d Cir. 1997)).

B. Law Governing Medical Devices

1. The Medical Device Amendments

The Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FFDCA") governs federal approval of medical devices for marketing. The MDA divides medical devices into three categories. Class III medical devices are those used for supporting or sustaining human life, or that are of substantial importance in preventing impairment of human health, or that present a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C). The Evergreen

Balloon Catheter is classified as a Class III medical device under the MDA.

In order to be marketed in the United States, Class III medical devices must undergo a Premarket Approval Process ("PMA"). The PMA process is a rigorous process involving the submission of extensive, detailed information regarding the safety and effectiveness of the device under review. The manufacturer must submit the following detailed information regarding the particular device:

> (A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;
> (B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;
> (C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of such device;
> (D) when identifying reference to any performance standard under section of 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;
> (E) such samples of such device and of components thereof as the Secretary may reasonable require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning

> the location of one or more such devices readily available for examination and testing;
> (F) specimens of the labeling proposed to be used for such device; and
> (G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title may require.

21 U.S.C. § 360e(c)(1).

Once a manufacturer has submitted this information, the Food and Drug Administration ("FDA") spends approximately 1,200 hours reviewing the application. If it determines that the manufacturer has provided reasonable assurances of the device's safety, it issues an order allowing the device to be marketed as approved. Any changes or modifications to the labeling, manufacturing or design of the device that affects its safety or effectiveness must be approved by the FDA before being implemented. If unapproved changes are implemented, the FDA's approval of the device may be withdrawn. 21 U.S.C. § 360e(e)(1); 21 C.F.R. § 814.80.

There are a few exceptions to the PMA process under which medical devices may be marketed without any direct inquiry into the device's safety and effectiveness. The MDA contains a grandfather provision, allowing devices on the market prior to 1976 to remain on the market until the FDA has had an opportunity to review the device's safety. 21 U.S.C. § 360e(b)(1)(a). Investigational devices are exempted from the PMA process and submitted to an investifational device exemption ("IDE") process, designed to encourage, "the discovery and development of useful devices intended for human use." 21 U.S.C. § 360j(g). In addition, devices that are

"substantially equivalent" to devices already on the market may avoid the PMA process. 21 U.S.C. § 360e(b)(1)(B). The process by which substantially equivalent devices are marketed is referred to as the "premarket notification" or the "§ 510(k)" process. Under this process, the manufacturer submits limited information about the device and the FDA performs a cursory review of the device, comparing the new device to a preexisting device. While the FDA spends about 1,200 hours on a PMA review, it spends only about 20 hours on a § 510(k) review. See Medtronic. V. Lohr, 518 U.S. 470, 478-79 (1996).

The MDA expressly preempts certain state law requirements in § 360(a), which states that

> Except as provided in subsection (b) of this section, no State or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement–
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C.§ 360(a).

2. Medtronic v. Lohr

In Lohr, a divided Supreme Court considered whether the MDA preempted state-law based tort claims regarding the design, labeling and safety of a pacemaker that had been approved under the MDA pursuant to the § 510(k) process. A majority of the Justices, following parts of an opinion written by Justice Stevens, found that the plaintiff's state law claims

were not preempted under the circumstances. However, the Court also engaged in an extensive analysis of the MDA and the effect of its preemption provision. The Court split in its analysis of the MDA, with four Justices joining the majority opinion in its entirety, four Justices joining an opinion by Justice O'Connor, concurring in part and dissecting in part, and Justice Breyer drafting his own concurring opinion in which he sides with the majority's outcome but also expresses agreement with some analysis in the O'Connor opinion.

The Stevens majority analyzed § 360(k) in conjunction with 21 C.F.R. 808.1(d) in order to determine the circumstances under which a state-law requirement would be preempted by the MDA. First, the majority found that in order for preemption to apply, the FDA must have established "specific counterpart regulations or there [must be] other specific requirements applicable to a particular device under the [MDA]." Lohr, 518 U.S. at 498. The majority also found that there must be a specific state requirement "with respect to" medical devices and relating to "the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device." Id. at 500. Preemption applies when the state requirements for the device are "different from, or in addition to" the federal requirements for the device. 21 U.S.C. § 360k(a); Id. A majority of the Supreme Court agreed that these general standards apply to determinations of whether a state-law requirement regarding a medical device is preempted by the MDA. However, what constitutes a "requirement," under federal and state law, and the situations in which the requirements are considered to conflict were hotly contested issues among the Justices.

The Supreme Court Justices diverged in their opinions as to whether a common law tort action brought under state law can

be considered a state requirement for preemption purposes under the MDA. A plurality of the Justices, led by Justice Stevens, found that "it will be rare indeed" for a state common law caus of action to be preempted, since such a claim does not establish the necessary "substantive requirement for a specific device." 21 C.F.R. 808.1(d)(6)(ii); Id. at 502-03. However, a majority of the Justices, including the dissenting Justices and Justice Breyer, disagreed. Justice Breyer summarized the views of this majority by stating that "[o]ne can reasonably read the word 'requirement' as including the legal requirements that grow out of the application . . . of a State's tort law." Id. at 503 (Breyer, J., concurring); see also id. at 509 (O'Connor, J., concurring in part and dissenting in part) ("[S]tate common-law damages actions do impose 'requirements' and are therefore pre-empted when such requirements would differ from those imposed by the [MDA]"). State common law actions, therefore, can be considered state "requirements" for purposes of preemption under the MDA. See, e.g., Brooks v. Howmedica, Inc., 273 F.3d 785, 795 (8th Cir. 2001) (analyzing Lohr and noting that a majority of the Justices in that action agreed that state common law claims can be considered state requirements for preemption purposes).

The Lohr decision is generally understood to hold that the MDA preempts common law claims to the extent they conflict with specific federal requirements. See id. In Lohr, the Stevens majority found that there was no conflict between the plaintiff's state common law claims and the federal labeling and manufacturing requirements for the pacemaker at issue, and thus plaintiff's state claims were not preempted by federal law. Lohr, 518 U.S. at 501. The Lohr court reached this decision in large part because the device at issue had been subject only to the minimal, non-safety related § 510(k) process. Section § 510(k) institutes a requirement only that the device at issue be "substantially similar" to a device already on the market. It

does not address the safety of the device. Since the Lohr plaintiffs' common law claims challenged the safety of the device at issue, there was no clear conflict between the plaintiffs' claims and the federal requirements for the device under § 510(k). Although there was no conflict in the Lohr action itself, the Stevens majority implies that safety-related conflicts may arise in other actions. Justice Stevens writes that Lohr is "unlike a case in which the Federal Government has weighed the competing interests relevant to a particular requirement . . . and implemented [its] conclusion via a specific mandate on manufacturers and producers." Id. at 501; see also id. at 493 (noting that the federal requirements in the Lohr case did not cover the safety of the device at issue of "'require' Medtronics' pacemaker to take any particular form for any particular reason," instead the § 510(k) process required Medtronic to comply only with "general standards").

3. Federal Court Decisions Post-Lohr

One issue left unresolved by Lohr is what type of federal rule or regulation constitutes a federal "requirement" for preemption purposes. While the Supreme Court in Lohr did not specifically consider whether the PMA process imposed a specific federal requirements sufficient to preempt state law requirements, a majority of courts following Lohr have found that the PMA process does impose specific federal safety requirements. See, e.g., Martin v. Medtronic, Inc., 254 F.3d 573, 585 (5th Cir. 2001) (finding that state torn claims relating to design defect, negligence and failure to warn are preempted by the MDA when device was subject to PMA process); Mitchell v. Collagen Corp., 126 F.3d 902, 905 (7th Cir. 1997) (reconsidering prior decision in light of Lohr and finding plaintiff's claims of strict liability, negligence and mislabeling preempted by the MDA when device was subject to PMA